

US3542332 (Prod: George Washington University)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:11:57

All time stamps listed in this document are displayed in GMT

US3542332

Form: Participant Creation

Data signed: (b) (4) 16 Oct 2020 13:16:27

Generated On: 10 Jun 2021 08:11:57

Participant ID

US3542332

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

US3542332

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 16 Oct 2020 13:16:27

Generated On: 10 Jun 2021 08:11:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 16 Oct 2020 13:16:27

Generated On: 10 Jun 2021 08:11:57

Date of Birth (MMM yyyy)	(b) (6) 1964
Age	56
Age Units	YEARS
Age (Derived)	56
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 16 Oct 2020 13:16:27

Generated On: 10 Jun 2021 08:11:57

Date of Informed Consent (<i>dd MMM yyyy</i>)	9 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input checked="" type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 16 Oct 2020 13:16:27

Generated On: 10 Jun 2021 08:11:57

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 16 Oct 2020 13:16:27

Generated On: 10 Jun 2021 08:11:57

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 08 Feb 2021 01:55:42

Generated On: 10 Jun 2021 08:11:57

Condition	SEIZURE DISORDER
Start date (dd MMM yyyy)	UN FEB 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	FEB 1998
Start Year (derived)	1998
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 08 Feb 2021 01:55:42

Generated On: 10 Jun 2021 08:11:57

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 08 Feb 2021 01:55:42

Generated On: 10 Jun 2021 08:11:57

Condition	L SIDED WEAKNESS SECONDARY TO CVA
Start date (dd MMM yyyy)	UN JAN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3542332

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 08 Feb 2021 01:55:42

Generated On: 10 Jun 2021 08:11:57

Condition	HIGH CHOLESTEROL
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 08 Feb 2021 01:55:42

Generated On: 10 Jun 2021 08:11:57

Condition	IMPLANTED CARDIAC MONITOR TO DETECT ARRHYTHMIAS
Start date (dd MMM yyyy)	UN JAN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 08 Feb 2021 01:55:42

Generated On: 10 Jun 2021 08:11:57

Condition	CVA
Start date (dd MMM yyyy)	UN JAN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JAN 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 08 Feb 2021 01:55:42

Generated On: 10 Jun 2021 08:11:57

Condition	RIGH HAND OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 16 Oct 2020 13:16:27

Generated On: 10 Jun 2021 08:11:57

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 OCT 2020
Time of assessment (00:00-23:59)	11:06 (24 HR)
Vital Signs Date and Time (derived)	09 OCT 2020 11:06
Height (xxx.x)	187 cm
Weight (xxx.x)	205 lb
BMI (xxx.x)	26.64698 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:35:22

Generated On: 10 Jun 2021 08:11:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 OCT 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Oct 2020 13:16:27

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

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) 16 Oct 2020 13:16:27

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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) 16 Oct 2020 13:16:27

Generated On: 10 Jun 2021 08:11:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Oct 2020 13:16:27

Generated On: 10 Jun 2021 08:11:57

What was the date of randomization? (dd MMM yyyy) 09 OCT 2020

What was the participant's randomization number? 116745

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) 16 Oct 2020 13:16:27

Generated On: 10 Jun 2021 08:11:57

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) 16 Oct 2020 13:16:27

Generated On: 10 Jun 2021 08:11:57

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 OCT 2020
Time of assessment (00:00-23:59)	11:06 (24 HR)
Vital Signs Date and Time (derived)	09 OCT 2020 11:06
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Oct 2020 13:16:27

Generated On: 10 Jun 2021 08:11:57

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 OCT 2020
Time of assessment (00:00-23:59)	12:46 (24 HR)
Vital Signs Date and Time (derived)	09 OCT 2020 12:46
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	46 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:35:22

Generated On: 10 Jun 2021 08:11:57

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Oct 2020 13:16:27

Generated On: 10 Jun 2021 08:11:57

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) 9 OCT 2020

What was the treatment time? (00:00-23:59) 12:16 (24 HR)

Treatment Date and Time (derived) 9 OCT 2020 12:16

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) 16 Oct 2020 13:16:27

Generated On: 10 Jun 2021 08:11:57

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	09 OCT 2020
Collection time (00:00-23:59)	11:45 (24 HR)
Collection date and time (derived)	09 OCT 2020 11:45

US3542332

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Oct 2020 13:16:27

Generated On: 10 Jun 2021 08:11:57

Collection date (dd MMM yyyy)			09 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:52	09 OCT 2020 11:52
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Oct 2020 13:16:27

Generated On: 10 Jun 2021 08:11:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:11:57

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 OCT 2020 12:47

PC Open Date & Time

09 OCT 2020 12:36

PC Close Date & Time

09 OCT 2020 15:06

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.1 °F

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

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

PC Time Stamp	09 OCT 2020 19:48
PC Open Date & Time	09 OCT 2020 16:01
PC Close Date & Time	10 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:11:57

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

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

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 OCT 2020 19:48

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 OCT 2020 06:58

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 OCT 2020 00:28

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:11:57

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 OCT 2020 20:09

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

15 OCT 2020 22:34

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 OCT 2020 12:48

PC Open Date & Time

09 OCT 2020 12:36

PC Close Date & Time

09 OCT 2020 15:06

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:11:57

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

09 OCT 2020 19:50

PC Open Date & Time

09 OCT 2020 16:01

PC Close Date & Time

10 OCT 2020 11:59

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:11:57

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

11 OCT 2020 19:51

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:11:57

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

13 OCT 2020 06:59

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 OCT 2020 00:29

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:11:57

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

14 OCT 2020 20:10

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:11:57

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

15 OCT 2020 22:36

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:57

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

No ☒

Yes ☐

PC Time stamp	09 OCT 2020 12:49
PC Open Date & Time	09 OCT 2020 12:36
PC Close Date & Time	09 OCT 2020 15:06

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:57

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

No ☒

Yes ☐

PC Time stamp	09 OCT 2020 19:51
PC Open Date & Time	09 OCT 2020 16:01
PC Close Date & Time	10 OCT 2020 11:59

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:57

Yes ☐

PC Time stamp

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:57

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 19:53
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:57

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 07:00
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 2047

EAB) (1725)

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:57

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 00:32
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

58 of 2047

EAB) (1725)

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:57

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 22:38
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3542332

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Oct 2020 19:07:06

Generated On: 10 Jun 2021 08:11:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

LEFT VOICEMAIL

If Contact Not Made, please provide Comments

US3542332

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 21 Oct 2020 19:07:06

Generated On: 10 Jun 2021 08:11:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542332

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 30 Oct 2020 02:06:28

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 30 Oct 2020 02:06:28

Generated On: 10 Jun 2021 08:11:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542332

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Nov 2020 22:32:00

Generated On: 10 Jun 2021 08:11:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542332

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Nov 2020 22:32:00

Generated On: 10 Jun 2021 08:11:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542332

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Nov 2020 16:54:52

Generated On: 10 Jun 2021 08:11:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3542332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Nov 2020 16:54:52

Generated On: 10 Jun 2021 08:11:57

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 NOV 2020
Time of assessment (00:00-23:59)	10:59 (24 HR)
Vital Signs Date and Time (derived)	12 NOV 2020 10:59
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3542332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Nov 2020 16:54:52

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Nov 2020 16:54:52

Generated On: 10 Jun 2021 08:11:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 NOV 2020

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

US3542332

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 21 Nov 2020 16:54:52

Generated On: 10 Jun 2021 08:11:57

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 SAE OF WORSENING SEIZURE DISORDER ONGOING.

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? _____

US3542332

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Nov 2020 16:54:52

Generated On: 10 Jun 2021 08:11:57

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 NOV 2020

Collection time (00:00-23:59)

11:12 (24 HR)

Collection date and time (derived)

12 NOV 2020 11:12

US3542332

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Nov 2020 16:54:52

Generated On: 10 Jun 2021 08:11:57

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		

US3542332

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 21 Nov 2020 16:54:52

Generated On: 10 Jun 2021 08:11:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542332

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Nov 2020 16:54:52

Generated On: 10 Jun 2021 08:11:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542332

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Nov 2020 16:54:52

Generated On: 10 Jun 2021 08:11:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542332

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 10 Dec 2020 16:33:20

Generated On: 10 Jun 2021 08:11:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542332

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 10 Dec 2020 16:33:20

Generated On: 10 Jun 2021 08:11:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542332

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 10 Dec 2020 16:33:20

Generated On: 10 Jun 2021 08:11:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542332

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 10 Dec 2020 16:33:20

Generated On: 10 Jun 2021 08:11:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542332

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 18 Dec 2020 16:21:39

Generated On: 10 Jun 2021 08:11:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3542332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Dec 2020 16:21:39

Generated On: 10 Jun 2021 08:11:57

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3542332

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Dec 2020 16:21:39

Generated On: 10 Jun 2021 08:11:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 DEC 2020

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

US3542332

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Dec 2020 16:21:39

Generated On: 10 Jun 2021 08:11:57

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 DEC 2020
Collection time (00:00-23:59)	09:30 (24 HR)
Collection date and time (derived)	14 DEC 2020 09:30

US3542332

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 18 Dec 2020 16:21:39

Generated On: 10 Jun 2021 08:11:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

10 DEC 2020 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

17 DEC 2020 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

24 DEC 2020 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

31 DEC 2020 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 JAN 2021 06:37:50
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

14 JAN 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Open Date & Time](#)

17 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Open Date & Time](#)

31 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Open Date & Time](#)

07 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Open Date & Time](#)

14 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 00:05:58

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

04 MAR 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 MAR 2021 02:36:53
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 MAR 2021 01:16:06

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 MAR 2021 23:26:01

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 MAR 2021 06:24:13

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 APR 2021 13:51:22
Patient Cloud Open Date & Time	04 APR 2021 00:01
Patient Cloud Close Date & Time	08 APR 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

15 APR 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Open Date & Time](#)

18 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

29 APR 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Open Date & Time](#)

02 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 SEP 2021 00:01
Patient Cloud Close Date & Time	09 SEP 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 SEP 2021 00:01
Patient Cloud Close Date & Time	16 SEP 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

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20 JAN 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

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27 JAN 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

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03 FEB 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

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10 FEB 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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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24 FEB 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

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03 MAR 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

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

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

Date and time of submission

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10 MAR 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

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24 MAR 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

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31 MAR 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

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

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07 APR 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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14 APR 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

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09 JUN 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

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16 JUN 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2022 00:01
Patient Cloud Close Date & Time	20 OCT 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

17 NOV 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

01 DEC 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Open Date & Time](#)

04 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2022 23:59

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

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

[Patient Cloud Close Date & Time](#)

15 DEC 2022 23:59

US3542332

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:11:57

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		10 MAR 2021 02:37:50

US3542332

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 13 Jan 2021 03:52:45

Generated On: 10 Jun 2021 08:11:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542332

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 13 Jan 2021 03:52:45

Generated On: 10 Jun 2021 08:11:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542332

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 17:47:19

Generated On: 10 Jun 2021 08:11:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542332

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 17:47:19

Generated On: 10 Jun 2021 08:11:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542332

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 22:24:18

Generated On: 10 Jun 2021 08:11:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542332

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 22:24:18

Generated On: 10 Jun 2021 08:11:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542332

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 14 Apr 2021 17:59:56

Generated On: 10 Jun 2021 08:11:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 APR 2021

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

LEFT VOICEMAILS AT 11:23,
12:29, 12:57

If Contact Not Made, please provide Comments

US3542332

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 14 Apr 2021 17:59:56

Generated On: 10 Jun 2021 08:11:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542332

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:11:57

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID _____

US3542332

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:11:57

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.

US3542332

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:57

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

Collection date (<i>dd MMM yyyy</i>)	_____
Collection time (<i>00:00-23:59</i>)	_____
Collection date and time (derived)	_____

US3542332

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:57

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3542332

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:11:57

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3542332

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

Form: Visit Date

Data signed: (b) (4) 08 Feb 2021 01:55:42

Generated On: 10 Jun 2021 08:11:57

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

Visit date (dd MMM yyyy)	04 FEB 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3542332

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

Form: Unblinding

Data signed: (b) (4) 12 Mar 2021 22:53:14

Generated On: 10 Jun 2021 08:11:57

Date of updated informed consent (<i>dd MMM yyyy</i>)	04 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	04 FEB 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	1

US3542332

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 08 Feb 2021 01:55:42

Generated On: 10 Jun 2021 08:11:57

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3542332

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Feb 2021 01:55:42

Generated On: 10 Jun 2021 08:11:57

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 FEB 2021
Time of assessment (00:00-23:59)	09:46 (24 HR)
Vital Signs Date and Time (derived)	04 FEB 2021 09:46
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3542332

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Feb 2021 01:55:42

Generated On: 10 Jun 2021 08:11:57

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 FEB 2021
Time of assessment (00:00-23:59)	10:27 (24 HR)
Vital Signs Date and Time (derived)	04 FEB 2021 10:27
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3542332

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

Form: Physical Examination

Data signed: (b) (4) 08 Feb 2021 01:55:42

Generated On: 10 Jun 2021 08:11:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 FEB 2021

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

US3542332

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

Form: Exposure

Data signed: (b) (4) 08 Feb 2021 01:55:42

Generated On: 10 Jun 2021 08:11:57

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 04 FEB 2021

What was the treatment time? (00:00-23:59) 09:57 (24 HR)

Treatment Date and Time (derived) 04 FEB 2021 09:57

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

US3542332

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Feb 2021 01:55:42

Generated On: 10 Jun 2021 08:11:57

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 FEB 2021
Collection time (00:00-23:59)	09:54 (24 HR)
Collection date and time (derived)	04 FEB 2021 09:54

US3542332

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 08 Feb 2021 01:55:42

Generated On: 10 Jun 2021 08:11:57

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 FEB 2021
Collection time (00:00 - 23:59)	09:52
Collection Date and Time (derived)	04 FEB 2021 09:52

US3542332

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

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 01:55:42

Generated On: 10 Jun 2021 08:11:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542332

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:03:57

Generated On: 10 Jun 2021 08:11:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542332

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:03:57

Generated On: 10 Jun 2021 08:11:57

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3542332

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 06 Mar 2021 00:43:46

Generated On: 10 Jun 2021 08:11:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3542332

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Mar 2021 00:43:46

Generated On: 10 Jun 2021 08:11:57

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 MAR 2021
Time of assessment (00:00-23:59)	08:15 (24 HR)
Vital Signs Date and Time (derived)	05 MAR 2021 08:15
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3542332

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Mar 2021 00:43:46

Generated On: 10 Jun 2021 08:11:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 MAR 2021

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

US3542332

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Mar 2021 00:43:46

Generated On: 10 Jun 2021 08:11:57

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

05 MAR 2021

Collection time (00:00-23:59)

08:16 (24 HR)

Collection date and time (derived)

05 MAR 2021 08:16

US3542332

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Nov 2020 22:32:00

Generated On: 10 Jun 2021 08:11:57

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3542332

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 14:24:27

Generated On: 10 Jun 2021 08:11:57

AEID	USA-US084-2020-MRNA-1273-P30 1000004
Adverse event	EXACERBATION OF SEIZURE DISORDER
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	7 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	09 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	7 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	8 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 14:24:27

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 14:24:27

Generated On: 10 Jun 2021 08:11:57

PT WITH PMH OF SEIZURE
DISORDER REPORTS THAT HE
HAD 4 WITNESSED SEIZURES
ON 7-NOV-2020. NO HEAD
INJURY BUT STATES HE WAS
POST-ICTAL AND DOES NOT
RECALL ALL EVENTS OF
SEIZURE. HE WAS SEEN AT
LOCAL HOSPITAL AND
ADMITTED FOR FURTHER
WORK-UP (CT HEAD AND LABS)
AND MANAGEMENT. HE
REPORTS COMPLIANCE WITH
MEDICATIONS; LAST SEIZURE
WAS IN JUNE 2020.
LAB RESULTS FROM
07NOV2020:
SODIUM 141; POTASSIUM 4.1;
GLUCOSE 211; CALCIUM 9.6;
HEMOGLOBIN 13.7; WBC 10.5;
ETHANOL <10.0. CT OF HEAD
FROM 07NOV2020: NO ACUTE
INTRACRANIAL PATHOLOGY.

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

US3542332

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 14:24:27

Generated On: 10 Jun 2021 08:11:57

AEID

Adverse event

WORSENER SEIZURE
DISORDER

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)

21 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

21 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 14:24:27

Generated On: 10 Jun 2021 08:11:57

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 14:24:27

Generated On: 10 Jun 2021 08:11:57

AEID	
Adverse event	DIZZINESS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	02 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	02 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 14:24:27

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 14:24:27

Generated On: 10 Jun 2021 08:11:57

AEID	USA-US084-2020-MRNA-1273-P30 1000004
Adverse event	WORSENING OF SEIZURE DISORDER
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	13 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	12 APR 2021
Hospital Discharge Date (dd MMM yyyy)	13 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 14:24:27

Generated On: 10 Jun 2021 08:11:57

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

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 14:24:27

Generated On: 10 Jun 2021 08:11:57

PARTICIPANT WAS
HOSPITALIZED ON
12-13-APR-2021 FOR SEIZURE.
HE EXPERIENCED
BREAKTHROUGH SEIZURE ON
12-APR-2021 DUE TO
NON-COMPLIANCE WITH
KEPPRA.

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

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Oct 2020 13:16:27

Generated On: 10 Jun 2021 08:11:57

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

Yes ☒

No ☐

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

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication SEIZURE DISORDER

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

Name of Medication KEPPRA

Prophylaxis Yes ☐
No ☒

Indication SEIZURE DISORDER

Dose per administration 1500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	06 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Feb 2021 01:55:41

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Name of Medication ZONISAMIDE

Prophylaxis Yes ☐
No ☒

Indication SEIZURE DISORDER

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

FIVE TIMES PER DAY

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

Name of Medication SIMVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HIGH CHOLESTEROL

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication STROKE PREVENTION

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

Name of Medication CARBAMAZEPINE

Prophylaxis Yes ☐
No ☒

Indication SEIZURE DISORDER

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	08 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

Name of Medication ELIQUIS

Prophylaxis Yes ☒
No ☐

Indication STROKE PREVENTION

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

Name of Medication KEPPRA

Prophylaxis Yes ☐
No ☒

Indication WORSENING SEIZURE
DISORDER (LOADING DOSE)

Dose per administration 1.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

Name of Medication CABAMAZEPINE

Prophylaxis Yes ☐
No ☒

Indication WORSENING SEIZURE
DISORDER

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		04 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		04 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

Name of Medication ATIVAN

Prophylaxis Yes ☐
No ☒

Indication WORSENING SEIZURE
DISORDER

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication RIGHT HAND OSTEOARTHRITIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 6 HOURS AS NEEDED

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication HEALTH MAINTENANCE

Dose per administration UNKNOWN

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

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 09 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

Name of Medication KEPPRA

Prophylaxis Yes ☐
No ☒

Indication SEIZURE DISORDER

Dose per administration 1500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 09 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication RIGHT HAND OSTEOARTHRITIS

Dose per administration 800

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

THREE TIMES A DAY AS
NEEDED

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

Name of Medication KEPPRA

Prophylaxis Yes ☐
No ☒

Indication SEIZURE DISORDER

Dose per administration 2500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

Name of Medication KEPPRA (LOADING DOSE)

Prophylaxis Yes ☐
No ☒

Indication BREAKTHROUGH SEIZURE

Dose per administration UNKNOWN

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

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Feb 2021 01:55:41

Generated On: 10 Jun 2021 08:11:57

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	21 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	21 JAN 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

US3542332

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Mar 2021 04:13:25

Generated On: 10 Jun 2021 08:11:57

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3542332

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Mar 2021 04:13:25

Generated On: 10 Jun 2021 08:11:57

Procedure/Surgery date (<i>dd MMM</i> <i>yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
02 MAR 2021	CT HEAD	Adverse Event	

US3542332

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 10 Dec 2020 16:33:20

Generated On: 10 Jun 2021 08:11:57

Date of dosing discontinuation (dd MMM yyyy)	12 NOV 2020
--	-------------

Primary reason for dosing discontinuation	AE (specify) <input type="checkbox"/>
	SAE (specify) <input checked="" type="checkbox"/>
	Death <input type="checkbox"/>
	Lost To Follow-up <input type="checkbox"/>
	Physician decision (specify) <input type="checkbox"/>
	Pregnancy <input type="checkbox"/>
	Protocol deviation (specify) <input type="checkbox"/>
	Study Terminated By Sponsor <input type="checkbox"/>
	Withdrawal of consent by participant (specify) <input type="checkbox"/>
	Due to SARS-COV-2 <input type="checkbox"/>
	Other <input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	SAE #1
---	--------

US3542332

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:11:57

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 ☐

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 30 Apr 2021 14:24:28

Generated On: 10 Jun 2021 08:11:57

SAEID	USA-US084-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 30 Apr 2021 14:24:28

Generated On: 10 Jun 2021 08:11:57

SAEID	USA-US084-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	10/NOV/2020 22:08
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

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 30 Apr 2021 14:24:28

Generated On: 10 Jun 2021 08:11:57

SAEID	USA-US084-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	16/NOV/2020 09:14
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

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 30 Apr 2021 14:24:28

Generated On: 10 Jun 2021 08:11:57

SAEID	USA-US084-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	20/NOV/2020 09:42
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 30 Apr 2021 14:24:28

Generated On: 10 Jun 2021 08:11:57

SAEID	USA-US084-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	25/NOV/2020 16:33
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

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Data signed: (b) (4) 30 Apr 2021 14:24:28

Generated On: 10 Jun 2021 08:11:57

SAEID	USA-US084-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	28/DEC/2020 08:55
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Data signed: (b) (4) 30 Apr 2021 14:24:28

Generated On: 10 Jun 2021 08:11:57

SAEID	USA-US084-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	09/MAR/2021 13:04
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

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Data signed: (b) (4) 30 Apr 2021 14:24:28

Generated On: 10 Jun 2021 08:11:57

SAEID	USA-US084-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	30/APR/2021 06:22
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

US3542332 (Prod: George Washington University)

US3542332

Form: Participant Creation

Generated On: 10 Jun 2021 08:11:57

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:13:07
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'US3542332'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Oct 2020 15:17:39

US3542332

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:11:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Yes (Y)'	(b) (4) Elissa Malkin (b) (4)	09 Oct 2020 15:41:52

US3542332

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '09 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Oct 2020 15:17:40

US3542332

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Clinic (Clinic)'	(b) (4) Elissa Malkin (b) (4)	09 Oct 2020 15:41:52

US3542332

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:11:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered 'SCRN'	System	09 Oct 2020 15:41:52

US3542332

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:11:57

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered (b) (6) 1964'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Oct 2020 15:17:41

US3542332

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:11:57

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '56'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:07:58

US3542332

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:11:57

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered 'YEARS'	System	12 Oct 2020 17:07:58

US3542332

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:11:57

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered '56'	System	09 Oct 2020 15:42:18

US3542332

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:11:57

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Male (M)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:07:58

US3542332

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:11:57

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:07:58

US3542332

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:11:57

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '0'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:07:58

US3542332

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:11:57

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'I'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:07:58

US3542332

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:11:57

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '0'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:07:58

US3542332

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:11:57

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '0'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:07:58

US3542332

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:11:57

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '0'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:07:58

US3542332

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:11:57

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '0'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:07:58

US3542332

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:11:57

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:07:58

US3542332

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:11:57

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '0'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:07:58

US3542332

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:11:57

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '0'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:07:58

US3542332

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:11:57

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '9 Oct 2020'	(b) (4) Elissa Malkin (b) (4)	09 Oct 2020 15:42:18

US3542332

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered 'Oct 2020'	System	09 Oct 2020 15:42:18

US3542332

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered '2020'	System	09 Oct 2020 15:42:18

US3542332

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:11:57

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Amendment 4 (4)'	(b) (4) Elissa Malkin (b) (4)	09 Oct 2020 15:42:18

US3542332

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Yes (Y)'	(b) (4) Elissa Malkin (b) (4)	09 Oct 2020 15:42:18

US3542332

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:11:57

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) Elissa Malkin (b) (4) (b) (4)	09 Oct 2020 15:42:18

US3542332

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:11:57

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) Elissa Malkin (b) (4) (b) (4)	09 Oct 2020 15:42:18

US3542332

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:11:57

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'No (N)'	(b) (4) Elissa Malkin (b) (4)	09 Oct 2020 15:42:18

US3542332

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:11:57

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Oct 2020 15:17:40

US3542332

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:11:57

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered 'l'	System	09 Oct 2020 15:42:24

US3542332

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Yes (Y)'	(b) (4) Elissa Malkin (b) (4)	09 Oct 2020 15:42:24

US3542332

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:11:57

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:08:12

US3542332

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:11:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User coded data point as SOC: Nervous system disorders, HLGT: Seizures (incl subtypes), HLT: Seizures and seizure disorders NEC, PT: Seizure, LLT: Seizure - version MedDRA\23.0.	Coder Import (b) (4)	12 Oct 2020 17:10:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Oct 2020 17:10:20
Data point term sent to Coder	System	12 Oct 2020 17:09:57
User entered 'seizure disorder'	DeEnna Wedding (b) (4)	12 Oct 2020 17:09:03

US3542332

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'UN Feb 1998'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:09:03

US3542332

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:11:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '0'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:09:03

US3542332

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:11:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:09:03

US3542332

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:09:03

US3542332

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:11:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '0'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:09:03

US3542332

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered 'Feb 1998'	System	12 Oct 2020 17:09:03

US3542332

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:11:57

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered '1998'	System	12 Oct 2020 17:09:03

US3542332

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered empty.	System	12 Oct 2020 17:09:03

US3542332

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered empty.	System	12 Oct 2020 17:09:03

US3542332

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:11:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 17:10:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 17:10:19
Data point term sent to Coder	System	12 Oct 2020 17:09:57
User entered 'hypertension'	DeEnna Wedding (b) (4)	12 Oct 2020 17:09:18

US3542332

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'UN UNK 2012'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:09:18

US3542332

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:11:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '0'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:09:18

US3542332

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:11:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:09:18

US3542332

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:09:18

US3542332

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:11:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '0'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:09:18

US3542332

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered 'Jan 2012'	System	12 Oct 2020 17:09:18

US3542332

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:11:57

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered '2012'	System	12 Oct 2020 17:09:18

US3542332

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered empty.	System	12 Oct 2020 17:09:18

US3542332

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered empty.	System	12 Oct 2020 17:09:18

US3542332

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:11:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User coded data point as SOC: Nervous system disorders, HLGT: Movement disorders (incl parkinsonism), HLT: Paralysis and paresis (excl cranial nerve), PT: Hemiparesis, LLT: Muscle weakness left-sided - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 09:58:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 09:58:55
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
Data point term sent to Coder	(b) (4) System	12 Oct 2020 17:10:59
User entered 'L sided weakness secondary to CVA'	DeEnna Wedding (b) (4)	12 Oct 2020 17:10:10
	(b) (4)	

US3542332

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'UN Jan 2019'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:10:10

US3542332

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:11:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '0'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:10:10

US3542332

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:11:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:10:10

US3542332

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:10:10

US3542332

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:11:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '0'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:10:10

US3542332

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered 'Jan 2019'	System	12 Oct 2020 17:10:10

US3542332

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:11:57

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered '2019'	System	12 Oct 2020 17:10:10

US3542332

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered empty.	System	12 Oct 2020 17:10:10

US3542332

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered empty.	System	12 Oct 2020 17:10:10

US3542332

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:11:57

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User coded data point as SOC: Investigations, HLGT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 17:12:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 17:12:24
Data point term sent to Coder System	DeEnna Wedding (b) (4)	12 Oct 2020 17:11:01
User entered 'high cholesterol'	(b) (4)	12 Oct 2020 17:10:35

US3542332

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'UN UNK 2015'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:10:35

US3542332

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:11:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '0'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:10:35

US3542332

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:11:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:10:35

US3542332

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:10:35

US3542332

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:11:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '0'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:10:35

US3542332

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered 'Jan 2015'	System	12 Oct 2020 17:10:35

US3542332

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:11:57

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered '2015'	System	12 Oct 2020 17:10:35

US3542332

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered empty.	System	12 Oct 2020 17:10:35

US3542332

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered empty.	System	12 Oct 2020 17:10:35

US3542332

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:11:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac device therapeutic procedures, PT: Implantable cardiac monitor insertion, LLT: Implantable cardiac monitor insertion - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 17:34:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 17:34:27
Data point term sent to Coder	System	12 Oct 2020 17:12:03
User entered 'implanted cardiac monitor to detect arrhythmias'	DeEnna Wedding (b) (4)	12 Oct 2020 17:11:17

US3542332

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'UN Jan 2019'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:11:17

US3542332

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:11:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '0'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:11:17

US3542332

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:11:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User closed query 'Per DM CLR: Please review if this pertains to IMPLANTED CARDIAC MONITOR. If yes, please ensure to update the stop date of this surgical procedure. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 06:01:16
Query 'Per DM CLR: Please review if this pertains to IMPLANTED CARDIAC MONITOR. If yes, please ensure to update the stop date of this surgical procedure. Otherwise, provide clarification. ' answered with 'unknown when the monitor was placed; do not need to record on con procedure log because it occurred before study enrollment. ' (Site from DM).	Hira Qadir (b) (4) (b) (4)	15 Dec 2020 19:50:43
User opened query 'Per DM CLR: Please review if this pertains to IMPLANTED CARDIAC MONITOR. If yes, please ensure to update the stop date of this surgical procedure. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 02:36:28
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 13:16:28
User entered 'Yes (Y)'	DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:11:17

US3542332

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:11:17

US3542332

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:11:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '0'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:11:17

US3542332

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered 'Jan 2019'	System	12 Oct 2020 17:11:17

US3542332

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:11:57

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered '2019'	System	12 Oct 2020 17:11:17

US3542332

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered empty.	System	12 Oct 2020 17:11:17

US3542332

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered empty.	System	12 Oct 2020 17:11:17

US3542332

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:11:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: CVA - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 17:13:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 17:13:31
Data point term sent to Coder	System	12 Oct 2020 17:12:09
User entered 'CVA'	DeEnna Wedding (b) (4)	12 Oct 2020 17:11:41

US3542332

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'UN Jan 2019'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:11:41

US3542332

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:11:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '0'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:11:41

US3542332

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:11:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:11:41

US3542332

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'UN Jan 2019'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:11:41

US3542332

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:11:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '0'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:11:41
	(b) (4)	

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Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered 'Jan 2019'	System	12 Oct 2020 17:11:41

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Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:11:57

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered '2019'	System	12 Oct 2020 17:11:41

US3542332

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered 'Jan 2019'	System	12 Oct 2020 17:11:41

US3542332

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered '2019'	System	12 Oct 2020 17:11:41

US3542332

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:11:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hand osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 09:32:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 09:32:43
User signature succeeded.	David Diemert (b) (4) (b) (4)	08 Feb 2021 01:55:42
Data point term sent to Coder	System	05 Feb 2021 17:03:37
User entered 'Righ Hand Osteoarthritis'	(b) (4), (b) (6)	05 Feb 2021 17:02:42

US3542332

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'UN UNK 2015'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:02:42

US3542332

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:11:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:02:42

US3542332

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:11:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:02:42

US3542332

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:02:42

US3542332

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:11:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:02:42

US3542332

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered 'Jan 2015'	System	05 Feb 2021 17:02:42

US3542332

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:11:57

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered '2015'	System	05 Feb 2021 17:02:42

US3542332

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered empty.	System	05 Feb 2021 17:02:42

US3542332

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered empty.	System	05 Feb 2021 17:02:42

US3542332

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:12:37

US3542332

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '09 Oct 2020'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:12:37

US3542332

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '11:06'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:12:37

US3542332

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered '09 Oct 2020 11:06'	System	12 Oct 2020 17:12:37

US3542332

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '187' cm	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:12:37
DataPoint set to visible.	(b) (4) System	09 Oct 2020 15:42:24

US3542332

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '205' lb	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:12:37
DataPoint set to visible.	(b) (4) System	09 Oct 2020 15:42:24

US3542332

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered '26.64698'	System	12 Oct 2020 17:12:37
DataPoint set to visible.	System	09 Oct 2020 15:42:24

US3542332

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered 'kg/m2'	System	12 Oct 2020 17:12:37
DataPoint set to visible.	System	09 Oct 2020 15:42:24

US3542332

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered missing code ND - Not Done.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:12:37
	(b) (4)	

US3542332

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:12:37
	(b) (4)	

US3542332

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:12:37

US3542332

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered missing code ND - Not Done.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:12:37

US3542332

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered 'bpm'	System	12 Oct 2020 17:12:37

US3542332

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered missing code ND - Not Done.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:12:37

US3542332

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered 'breaths/min'	System	12 Oct 2020 17:12:37

US3542332

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered missing code ND - Not Done.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:12:37
	(b) (4)	

US3542332

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered 'mmHg'	System	12 Oct 2020 17:12:37

US3542332

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered missing code ND - Not Done.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:12:37

US3542332

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered 'mmHg'	System	12 Oct 2020 17:12:37

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30

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Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:11:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	12 Feb 2021 19:35:22
Signature has been broken.	(b) (4) Erika Faust (b) (4)	11 Feb 2021 18:11:27
User entered 'Yes (Y)' reason for change: New Information	(b) (4) Erika Faust (b) (4)	11 Feb 2021 18:11:27
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:12:45
	(b) (4)	

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Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:11:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	12 Feb 2021 19:35:22
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	11 Feb 2021 18:11:27
User entered '09 Oct 2020' reason for change: New Information	(b) (4)	
	Erika Faust (b) (4)	11 Feb 2021 18:11:27
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4)	
	DeEnna Wedding (b) (4)	12 Oct 2020 17:12:45
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:13:41

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:13:41

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:13:41

US3542332

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:13:41

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:57

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:13:41

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:13:41

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:13:41

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:13:41

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:13:41
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:13:41

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:13:41

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:57

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:13:41

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:57

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:13:41
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:57

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '0'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:13:41

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '0'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:13:41

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '0'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:13:41

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'I'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:13:41

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '0'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:13:41

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '0'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:13:41

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:57

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '0'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:13:41

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:11:57

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:13:41
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:11:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Yes (Y)'	(b) (4) Elissa Malkin (b) (4)	09 Oct 2020 15:42:36

US3542332

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '9 Oct 2020'	(b) (4) Elissa Malkin (b) (4)	09 Oct 2020 15:42:36

US3542332

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Clinic (Clinic)'	(b) (4) Elissa Malkin (b) (4)	09 Oct 2020 15:42:36

US3542332

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:11:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User entered 'VISIT1'	System	09 Oct 2020 15:42:36

US3542332

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '09 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Oct 2020 15:42:44

US3542332

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '116745'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Oct 2020 15:42:44

US3542332

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Oct 2020 15:42:44

US3542332

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:15:03

US3542332

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:15:03

US3542332

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
	(b) (4)	
User entered 'No (N)'	DeEnna Wedding (b) (4)	12 Oct 2020 17:15:03
	(b) (4)	

US3542332

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:11:57

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:23
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 13:16:28
User entered 'No (N)'	DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:15:03

US3542332

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:11:57

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:15:03

US3542332

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'No (N)'	(b) (4)	
	DeEnna Wedding (b) (4)	12 Oct 2020 17:15:03
	(b) (4)	
DataPoint set to visible.	System	09 Oct 2020 15:42:18

US3542332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:11:57

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered missing code ND - Not Done.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:15:54

US3542332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:11:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered missing code ND - Not Done.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:15:54

US3542332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:11:57

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered missing code ND - Not Done.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:15:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:11:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered missing code ND - Not Done.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:15:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User accepted default value 'Pre-Dose (PREDOSE)'	DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:15:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:15:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '09 Oct 2020'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:15:54
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '11:06'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:15:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User entered '09 Oct 2020 11:06'	System	12 Oct 2020 17:15:54

US3542332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
	(b) (4)	
User entered '97.6' F	DeEnna Wedding (b) (4)	12 Oct 2020 17:15:54
	(b) (4)	

US3542332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
	(b) (4)	
User entered 'Oral (Oral)'	DeEnna Wedding (b) (4)	12 Oct 2020 17:15:54
	(b) (4)	

US3542332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:15:54

US3542332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '54'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:15:54

US3542332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User entered 'bpm'	System	12 Oct 2020 17:15:54

US3542332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '16'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:15:54

US3542332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User entered 'breaths/min'	System	12 Oct 2020 17:15:54

US3542332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '127'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:15:54

US3542332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User entered 'mmHg'	System	12 Oct 2020 17:15:54

US3542332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '77'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:15:54

US3542332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User entered 'mmHg'	System	12 Oct 2020 17:15:54

US3542332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:11:57

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered missing code ND - Not Done.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:15:54

US3542332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:11:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered missing code ND - Not Done.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:15:54

US3542332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User accepted default value 'Post-Dose (POSTDOSE)'	DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:16:55

US3542332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:16:55

US3542332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '09 Oct 2020'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:16:55
	(b) (4)	

US3542332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '12:46'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:16:55

US3542332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User entered '09 Oct 2020 12:46'	System	12 Oct 2020 17:16:55

US3542332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
	(b) (4)	
User entered '98.0' F	DeEnna Wedding (b) (4)	12 Oct 2020 17:16:55
	(b) (4)	

US3542332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Oral (Oral)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:16:55
	(b) (4)	

US3542332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:16:55

US3542332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
	(b) (4)	
User entered '46'	DeEnna Wedding (b) (4)	12 Oct 2020 17:16:55
	(b) (4)	

US3542332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User entered 'bpm'	System	12 Oct 2020 17:16:55

US3542332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 13:16:28
User entered '16'	DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:16:55

US3542332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User entered 'breaths/min'	System	12 Oct 2020 17:16:55

US3542332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '147'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:16:55

US3542332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User entered 'mmHg'	System	12 Oct 2020 17:16:55

US3542332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
	(b) (4)	
User entered '91'	DeEnna Wedding (b) (4)	12 Oct 2020 17:16:55
	(b) (4)	

US3542332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User entered 'mmHg'	System	12 Oct 2020 17:16:55

US3542332

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:11:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:50
User signature succeeded.	David Diemert (b) (4)	12 Feb 2021 19:35:22
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	11 Feb 2021 18:11:50
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Erika Faust (b) (4)	11 Feb 2021 18:11:50
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Yes (Y)'	(b) (4)	
	DeEnna Wedding (b) (4)	12 Oct 2020 17:17:04
	(b) (4)	

US3542332

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:11:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:50
User signature succeeded.	David Diemert (b) (4)	12 Feb 2021 19:35:22
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	11 Feb 2021 18:11:50
User entered empty; reason for change New Information	(b) (4)	
	Erika Faust (b) (4)	11 Feb 2021 18:11:50
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '09 Oct 2020'	(b) (4)	
	DeEnna Wedding (b) (4)	12 Oct 2020 17:17:04
	(b) (4)	

US3542332

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:11:57

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:18
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Yes (Y)'	(b) (4) (D) (4), (b) (6)	09 Oct 2020 16:31:29

US3542332

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:11:57

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:18
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) (D) (4), (b) (6)	09 Oct 2020 16:31:29

US3542332

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:18
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) (D) (4), (b) (6)	09 Oct 2020 16:31:29

US3542332

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:11:57

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:18
User entered 'MRNA-1273 OR PLACEBO'	System	09 Oct 2020 16:31:29

US3542332

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:11:57

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:18
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '9 Oct 2020'	(b) (4) (D) (4), (b) (6)	09 Oct 2020 16:31:29

US3542332

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:18
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '12:16'	(b) (4) (D) (4), (b) (6)	09 Oct 2020 16:31:29

US3542332

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:18
User entered '9 Oct 2020 12:16'	System	09 Oct 2020 16:31:29

US3542332

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:18
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (D) (4), (b) (6)	09 Oct 2020 16:31:29

US3542332

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:18
User entered 'ONCE'	System	09 Oct 2020 16:31:29

US3542332

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:11:57

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:18
User entered 'INTRAMUSCULAR'	System	09 Oct 2020 16:31:29

US3542332

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:50
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:17:33

US3542332

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:50
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '09 Oct 2020'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:17:33
	(b) (4)	

US3542332

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:57

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:50
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 13:16:28
User entered '11:45'	DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:17:33

US3542332

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:50
User entered '09 Oct 2020 11:45'	System	12 Oct 2020 17:17:33

US3542332

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:11:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:19
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '09 Oct 2020'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:17:49
	(b) (4)	

US3542332

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:11:57

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:19
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:17:49

US3542332

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:11:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:19
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:17:49

US3542332

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:11:57

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:19
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '11:52'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:17:49

US3542332

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:11:57

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:19
User entered '09 Oct 2020 11:52'	System	12 Oct 2020 17:17:49

US3542332

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:11:57

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:19
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:17:49

US3542332

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:11:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:19
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
	(b) (4)	
User entered 'No (N)'	DeEnna Wedding (b) (4)	12 Oct 2020 17:17:49
	(b) (4)	

US3542332

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:11:57

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:19
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:17:49

US3542332

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:11:57

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:19
User entered empty.	System	12 Oct 2020 17:17:49

US3542332

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:08
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:17:59

US3542332

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:11:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:08
User entered 'I'	System	12 Oct 2020 17:17:59

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:11:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-09T12:46:40', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '0e5fc908-d4d7-4f10-b162-9f894d8d82bc' User entered 'Yes (Y)'	System	09 Oct 2020 16:47:30
	System	09 Oct 2020 16:47:30

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:11:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-09T12:46:56', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '0e5fc908-d4d7-4f10-b162-9f894d8d82bc' User entered '98.0'	System	09 Oct 2020 16:47:30
	System	09 Oct 2020 16:47:30

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-09T12:47:09', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '0e5fc908-d4d7-4f10-b162-9f894d8d82bc'	System	09 Oct 2020 16:47:30
User entered 'No (N)'	System	09 Oct 2020 16:47:30

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:11:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-09T12:47:28', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '0e5fc908-d4d7-4f10-b162-9f894d8d82bc' User entered '09 Oct 2020 12:47'	System	09 Oct 2020 16:47:30
	System	09 Oct 2020 16:47:30

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:11:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '09 Oct 2020 12:36'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:11:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '09 Oct 2020 15:06'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:11:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-09T19:47:13', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '6455eb8b-16de-418b-94ea-fba16c77a21b' User entered 'Yes (Y)'	System	09 Oct 2020 23:48:25
	System	09 Oct 2020 23:48:25

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:11:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-09T19:47:33', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '6455eb8b-16de-418b-94ea-fba16c77a21b' User entered '97.1'	System	09 Oct 2020 23:48:25
	System	09 Oct 2020 23:48:25

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-09T19:47:47', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '6455eb8b-16de-418b-94ea-fba16c77a21b' User entered 'No (N)'	System	09 Oct 2020 23:48:25
	System	09 Oct 2020 23:48:25

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:11:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-09T19:48:23', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '6455eb8b-16de-418b-94ea-fba16c77a21b' User entered '09 Oct 2020 19:48'	System	09 Oct 2020 23:48:25
	System	09 Oct 2020 23:48:25

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:11:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '09 Oct 2020 16:01'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:11:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 2'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:11:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:11:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:11:57

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:11:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:11:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:11:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 3'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:11:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-11T19:47:50', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '022015ba-791b-4fcb-8e33-65bc5e3fdc3f' User entered 'Yes (Y)'	System	11 Oct 2020 23:49:00
	System	11 Oct 2020 23:49:00

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:11:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-11T19:48:23', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '022015ba-791b-4fcb-8e33-65bc5e3fdc3f' User entered '98.0'	System	11 Oct 2020 23:49:00
	System	11 Oct 2020 23:49:00

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-11T19:48:39', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '022015ba-791b-4fcb-8e33-65bc5e3fdc3f' User entered 'No (N)'	System	11 Oct 2020 23:49:00
	System	11 Oct 2020 23:49:00

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:11:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-11T19:48:56', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '022015ba-791b-4fcb-8e33-65bc5e3fdc3f' User entered '11 Oct 2020 19:48'	System	11 Oct 2020 23:49:00
	System	11 Oct 2020 23:49:00

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:11:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:11:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 4'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:11:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-13T06:57:48', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '13f0f518-2daf-4ece-a4d0-7b631f914cb1' User entered 'Yes (Y)'	System	13 Oct 2020 10:58:20
	System	13 Oct 2020 10:58:20

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:11:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-13T06:57:58', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '13f0f518-2daf-4ece-a4d0-7b631f914cb1' User entered '98.3'	System	13 Oct 2020 10:58:20
	System	13 Oct 2020 10:58:20

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-13T06:58:10', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '13f0f518-2daf-4ece-a4d0-7b631f914cb1'	System	13 Oct 2020 10:58:20
User entered 'No (N)'	System	13 Oct 2020 10:58:20

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:11:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-13T06:58:15', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '13f0f518-2daf-4ece-a4d0-7b631f914cb1'	System	13 Oct 2020 10:58:20
User entered '13 Oct 2020 06:58'	System	13 Oct 2020 10:58:20

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:11:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '12 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:11:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '13 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 5'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:11:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-14T00:27:32', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'df120737-a48f-4f48-99ba-b5973962357c' User entered 'Yes (Y)'	System	14 Oct 2020 04:28:22
	System	14 Oct 2020 04:28:22

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:11:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-14T00:27:56', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'df120737-a48f-4f48-99ba-b5973962357c' User entered '96.8'	System	14 Oct 2020 04:28:22
	System	14 Oct 2020 04:28:22

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-14T00:28:06', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'df120737-a48f-4f48-99ba-b5973962357c' User entered 'No (N)'	System	14 Oct 2020 04:28:22
	System	14 Oct 2020 04:28:22

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:11:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-14T00:28:18', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'df120737-a48f-4f48-99ba-b5973962357c' User entered '14 Oct 2020 00:28'	System	14 Oct 2020 04:28:22
	System	14 Oct 2020 04:28:22

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:11:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '13 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:11:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '14 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 6'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:11:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-14T20:09:02', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'e505ddeb-7454-4e23-89aa-9774ea02fb0c' User entered 'Yes (Y)'	System	20 Oct 2020 23:53:43
	System	20 Oct 2020 23:53:43

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:11:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-14T20:09:18', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'e505ddeb-7454-4e23-89aa-9774ea02fb0c' User entered '97.4'	System	20 Oct 2020 23:53:43
	System	20 Oct 2020 23:53:43

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-14T20:09:32', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'e505ddeb-7454-4e23-89aa-9774ea02fb0c' User entered 'No (N)'	System	20 Oct 2020 23:53:43
	System	20 Oct 2020 23:53:43

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:11:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-14T20:09:35', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'e505ddeb-7454-4e23-89aa-9774ea02fb0c' User entered '14 Oct 2020 20:09'	System	20 Oct 2020 23:53:43
	System	20 Oct 2020 23:53:43

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:11:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '14 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:11:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '15 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 7'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:11:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-15T22:33:45', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '5a8e34ea-0d66-497b-833c-9e622f5ebba7'	System	20 Oct 2020 23:53:44
User entered 'Yes (Y)'	System	20 Oct 2020 23:53:44

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:11:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-15T22:33:59', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '5a8e34ea-0d66-497b-833c-9e622f5ebba7' User entered '97.5'	System	20 Oct 2020 23:53:44
	System	20 Oct 2020 23:53:44

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-15T22:34:24', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '5a8e34ea-0d66-497b-833c-9e622f5ebba7'	System	20 Oct 2020 23:53:44
User entered 'No (N)'	System	20 Oct 2020 23:53:44

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:11:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-15T22:34:30', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '5a8e34ea-0d66-497b-833c-9e622f5ebba7' User entered '15 Oct 2020 22:34'	System	20 Oct 2020 23:53:44
	System	20 Oct 2020 23:53:44

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:11:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '15 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:11:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '16 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:11:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-09T12:47:56', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'd8cbaef0-bcc9-4bca-af3a-693b37cec44a'	System	09 Oct 2020 16:48:40
User entered 'None (1)'	System	09 Oct 2020 16:48:40

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:11:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-09T12:48:01', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'd8cbaef0-bcc9-4bca-af3a-693b37cec44a' User entered 'No (N)'	System	09 Oct 2020 16:48:40
	System	09 Oct 2020 16:48:40

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-09T12:48:21', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'd8cbaef0-bcc9-4bca-af3a-693b37cec44a' User entered 'No (N)'	System	09 Oct 2020 16:48:40
	System	09 Oct 2020 16:48:40

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:11:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-09T12:48:26', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'd8cbaef0-bcc9-4bca-af3a-693b37cec44a'	System	09 Oct 2020 16:48:40
User entered 'None (1)'	System	09 Oct 2020 16:48:40

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:11:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-09T12:48:37', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'd8cbaef0-bcc9-4bca-af3a-693b37cec44a' User entered '09 Oct 2020 12:48'	System	09 Oct 2020 16:48:40
	System	09 Oct 2020 16:48:40

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:11:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '09 Oct 2020 12:36'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:11:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '09 Oct 2020 15:06'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:11:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-09T19:49:23', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'ce161d72-6c1a-430c-a846-e3cfc3931218' User entered 'None (1)'	System	09 Oct 2020 23:50:07
	System	09 Oct 2020 23:50:07

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:11:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-09T19:49:33', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'ce161d72-6c1a-430c-a846-e3cfc3931218' User entered 'No (N)'	System	09 Oct 2020 23:50:07
	System	09 Oct 2020 23:50:07

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-09T19:49:42', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'ce161d72-6c1a-430c-a846-e3cfc3931218' User entered 'No (N)'	System	09 Oct 2020 23:50:07
	System	09 Oct 2020 23:50:07

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:11:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-09T19:49:56', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'ce161d72-6c1a-430c-a846-e3cfc3931218'	System	09 Oct 2020 23:50:07
User entered 'None (1)'	System	09 Oct 2020 23:50:07

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:11:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-09T19:50:03', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'ce161d72-6c1a-430c-a846-e3cfc3931218' User entered '09 Oct 2020 19:50'	System	09 Oct 2020 23:50:07
	System	09 Oct 2020 23:50:07

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:11:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '09 Oct 2020 16:01'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:11:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 2'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:11:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:11:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:11:57

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:11:57

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:11:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:11:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:11:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:11:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 3'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:11:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-11T19:50:14', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '77cd2782-d9ee-45d0-9de2-1fc3e181dc44'	System	11 Oct 2020 23:51:05
User entered 'None (1)'	System	11 Oct 2020 23:51:05

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:11:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-11T19:50:27', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '77cd2782-d9ee-45d0-9de2-1fc3e181dc44'	System	11 Oct 2020 23:51:05
User entered 'No (N)'	System	11 Oct 2020 23:51:05

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-11T19:50:34', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '77cd2782-d9ee-45d0-9de2-1fc3e181dc44'	System	11 Oct 2020 23:51:05
User entered 'No (N)'	System	11 Oct 2020 23:51:05

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:11:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-11T19:50:57', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '77cd2782-d9ee-45d0-9de2-1fc3e181dc44'	System	11 Oct 2020 23:51:05
User entered 'None (1)'	System	11 Oct 2020 23:51:05

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:11:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-11T19:51:02', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '77cd2782-d9ee-45d0-9de2-1fc3e181dc44'	System	11 Oct 2020 23:51:05
User entered '11 Oct 2020 19:51'	System	11 Oct 2020 23:51:05

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:11:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:11:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 4'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:11:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-13T06:58:36', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '4512bc26-974f-4813-b2dd-9b3f2dea1ab4' User entered 'None (1)'	System	13 Oct 2020 10:59:06
	System	13 Oct 2020 10:59:06

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:11:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-13T06:58:42', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '4512bc26-974f-4813-b2dd-9b3f2dea1ab4'	System	13 Oct 2020 10:59:06
User entered 'No (N)'	System	13 Oct 2020 10:59:06

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-13T06:58:46', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '4512bc26-974f-4813-b2dd-9b3f2dea1ab4'	System	13 Oct 2020 10:59:06
User entered 'No (N)'	System	13 Oct 2020 10:59:06

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:11:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-13T06:58:58', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '4512bc26-974f-4813-b2dd-9b3f2dea1ab4'	System	13 Oct 2020 10:59:06
User entered 'None (1)'	System	13 Oct 2020 10:59:06

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:11:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-13T06:59:02', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '4512bc26-974f-4813-b2dd-9b3f2dea1ab4' User entered '13 Oct 2020 06:59'	System	13 Oct 2020 10:59:06
	System	13 Oct 2020 10:59:06

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:11:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '12 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:11:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '13 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 5'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:11:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-14T00:28:42', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'abea6980-ff9b-405f-bc8d-695f549b6bc8' User entered 'None (1)'	System	14 Oct 2020 04:29:35
	System	14 Oct 2020 04:29:35

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:11:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-14T00:28:52', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'abea6980-ff9b-405f-bc8d-695f549b6bc8' User entered 'No (N)'	System	14 Oct 2020 04:29:35
	System	14 Oct 2020 04:29:35

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-14T00:29:08', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'abea6980-ff9b-405f-bc8d-695f549b6bc8' User entered 'No (N)'	System	14 Oct 2020 04:29:35
	System	14 Oct 2020 04:29:35

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:11:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-14T00:29:23', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'abea6980-ff9b-405f-bc8d-695f549b6bc8' User entered 'None (1)'	System	14 Oct 2020 04:29:35
	System	14 Oct 2020 04:29:35

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:11:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-14T00:29:31', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'abea6980-ff9b-405f-bc8d-695f549b6bc8' User entered '14 Oct 2020 00:29'	System	14 Oct 2020 04:29:35
	System	14 Oct 2020 04:29:35

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:11:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '13 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:11:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '14 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 6'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:11:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-14T20:09:55', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '4b48793b-5c93-4438-9282-730780d83e1e' User entered 'None (1)'	System	20 Oct 2020 23:53:44
	System	20 Oct 2020 23:53:44

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:11:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-14T20:10:07', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '4b48793b-5c93-4438-9282-730780d83e1e' User entered 'No (N)'	System	20 Oct 2020 23:53:44
	System	20 Oct 2020 23:53:44

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-14T20:10:19', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '4b48793b-5c93-4438-9282-730780d83e1e' User entered 'No (N)'	System	20 Oct 2020 23:53:44
	System	20 Oct 2020 23:53:44

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:11:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-14T20:10:34', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '4b48793b-5c93-4438-9282-730780d83e1e' User entered 'None (1)'	System	20 Oct 2020 23:53:44
	System	20 Oct 2020 23:53:44

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:11:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-14T20:10:38', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '4b48793b-5c93-4438-9282-730780d83e1e' User entered '14 Oct 2020 20:10'	System	20 Oct 2020 23:53:44
	System	20 Oct 2020 23:53:44

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:11:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '14 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:11:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '15 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 7'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:11:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-15T22:35:06', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'c9a9087f-f8a1-4fe8-9edb-48eb46d0b549'	System	20 Oct 2020 23:53:46
User entered 'None (1)'	System	20 Oct 2020 23:53:46

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:11:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-15T22:35:12', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'c9a9087f-f8a1-4fe8-9edb-48eb46d0b549'	System	20 Oct 2020 23:53:46
User entered 'No (N)'	System	20 Oct 2020 23:53:46

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-15T22:35:36', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'c9a9087f-f8a1-4fe8-9edb-48eb46d0b549'	System	20 Oct 2020 23:53:46
User entered 'No (N)'	System	20 Oct 2020 23:53:46

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:11:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-15T22:36:25', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'c9a9087f-f8a1-4fe8-9edb-48eb46d0b549'	System	20 Oct 2020 23:53:46
User entered 'None (1)'	System	20 Oct 2020 23:53:46

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:11:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-15T22:36:29', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'c9a9087f-f8a1-4fe8-9edb-48eb46d0b549' User entered '15 Oct 2020 22:36'	System	20 Oct 2020 23:53:46
	System	20 Oct 2020 23:53:46

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:11:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '15 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:11:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '16 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-09T12:49:13', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '02982577-0856-4c63-bbf6-14676dbec175' User entered 'None (0)'	System	09 Oct 2020 16:49:20
	System	09 Oct 2020 16:49:20

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-09T12:48:52', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '02982577-0856-4c63-bbf6-14676dbec175' User entered 'None (0)'	System	09 Oct 2020 16:49:20
	System	09 Oct 2020 16:49:20

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-09T12:48:56', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '02982577-0856-4c63-bbf6-14676dbec175' User entered 'None (0)'	System	09 Oct 2020 16:49:20
	System	09 Oct 2020 16:49:20

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-09T12:48:59', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '02982577-0856-4c63-bbf6-14676dbec175' User entered 'None (0)'	System	09 Oct 2020 16:49:20
	System	09 Oct 2020 16:49:20

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-09T12:49:02', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '02982577-0856-4c63-bbf6-14676dbec175' User entered 'None (0)'	System	09 Oct 2020 16:49:20
	System	09 Oct 2020 16:49:20

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-09T12:49:05', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '02982577-0856-4c63-bbf6-14676dbec175' User entered 'None (0)'	System	09 Oct 2020 16:49:20
	System	09 Oct 2020 16:49:20

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-09T12:49:09', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '02982577-0856-4c63-bbf6-14676dbec175' User entered 'No (N)'	System	09 Oct 2020 16:49:20
	System	09 Oct 2020 16:49:20

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-09T12:49:19', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '02982577-0856-4c63-bbf6-14676dbec175' User entered '09 Oct 2020 12:49'	System	09 Oct 2020 16:49:20
	System	09 Oct 2020 16:49:20

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '09 Oct 2020 12:36'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:11:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '09 Oct 2020 15:06'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-09T19:50:15', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '48b5b2f5-bc73-4a6a-9227-60950fc96585' User entered 'None (0)'	System	09 Oct 2020 23:51:51
	System	09 Oct 2020 23:51:51

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-09T19:50:30', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '48b5b2f5-bc73-4a6a-9227-60950fc96585' User entered 'None (0)'	System	09 Oct 2020 23:51:51
	System	09 Oct 2020 23:51:51

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-09T19:50:46', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '48b5b2f5-bc73-4a6a-9227-60950fc96585' User entered 'None (0)'	System	09 Oct 2020 23:51:51
	System	09 Oct 2020 23:51:51

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-09T19:51:07', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '48b5b2f5-bc73-4a6a-9227-60950fc96585' User entered 'None (0)'	System	09 Oct 2020 23:51:51
	System	09 Oct 2020 23:51:51

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-09T19:51:17', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '48b5b2f5-bc73-4a6a-9227-60950fc96585' User entered 'None (0)'	System	09 Oct 2020 23:51:51
	System	09 Oct 2020 23:51:51

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-09T19:51:29', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '48b5b2f5-bc73-4a6a-9227-60950fc96585' User entered 'None (0)'	System	09 Oct 2020 23:51:51
	System	09 Oct 2020 23:51:51

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-09T19:51:44', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '48b5b2f5-bc73-4a6a-9227-60950fc96585'	System	09 Oct 2020 23:51:51
User entered 'No (N)'	System	09 Oct 2020 23:51:51

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-09T19:51:49', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '48b5b2f5-bc73-4a6a-9227-60950fc96585' User entered '09 Oct 2020 19:51'	System	09 Oct 2020 23:51:51
	System	09 Oct 2020 23:51:51

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '09 Oct 2020 16:01'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:11:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 2'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:11:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 3'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-11T19:51:13', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '77d154f0-e7e3-4c0b-b9ad-f8dc9ef30d91' User entered 'None (0)'	System	11 Oct 2020 23:53:30
	System	11 Oct 2020 23:53:30

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-11T19:51:42', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '77d154f0-e7e3-4c0b-b9ad-f8dc9ef30d91' User entered 'None (0)'	System	11 Oct 2020 23:53:30
	System	11 Oct 2020 23:53:30

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-11T19:51:55', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '77d154f0-e7e3-4c0b-b9ad-f8dc9ef30d91' User entered 'None (0)'	System	11 Oct 2020 23:53:30
	System	11 Oct 2020 23:53:30

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-11T19:52:07', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '77d154f0-e7e3-4c0b-b9ad-f8dc9ef30d91' User entered 'None (0)'	System	11 Oct 2020 23:53:30
	System	11 Oct 2020 23:53:30

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-11T19:52:37', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '77d154f0-e7e3-4c0b-b9ad-f8dc9ef30d91' User entered 'None (0)'	System	11 Oct 2020 23:53:30
	System	11 Oct 2020 23:53:30

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-11T19:52:59', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '77d154f0-e7e3-4c0b-b9ad-f8dc9ef30d91' User entered 'None (0)'	System	11 Oct 2020 23:53:30
	System	11 Oct 2020 23:53:30

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-11T19:53:17', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '77d154f0-e7e3-4c0b-b9ad-f8dc9ef30d91'	System	11 Oct 2020 23:53:30
User entered 'No (N)'	System	11 Oct 2020 23:53:30

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-11T19:53:27', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '77d154f0-e7e3-4c0b-b9ad-f8dc9ef30d91' User entered '11 Oct 2020 19:53'	System	11 Oct 2020 23:53:30
	System	11 Oct 2020 23:53:30

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:11:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 4'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-13T06:59:09', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '6779416b-251b-4fff-ac1f-a8aae8a7ade0' User entered 'None (0)'	System	13 Oct 2020 11:00:39
	System	13 Oct 2020 11:00:39

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-13T06:59:34', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '6779416b-251b-4fff-ac1f-a8aae8a7ade0' User entered 'None (0)'	System	13 Oct 2020 11:00:39
	System	13 Oct 2020 11:00:39

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-13T07:00:00', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '6779416b-251b-4fff-ac1f-a8aae8a7ade0' User entered 'None (0)'	System	13 Oct 2020 11:00:39
	System	13 Oct 2020 11:00:39

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-13T07:00:09', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '6779416b-251b-4fff-ac1f-a8aae8a7ade0' User entered 'None (0)'	System	13 Oct 2020 11:00:39
	System	13 Oct 2020 11:00:39

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-13T07:00:17', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '6779416b-251b-4fff-ac1f-a8aae8a7ade0' User entered 'None (0)'	System	13 Oct 2020 11:00:39
	System	13 Oct 2020 11:00:39

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-13T07:00:22', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '6779416b-251b-4fff-ac1f-a8aae8a7ade0' User entered 'None (0)'	System	13 Oct 2020 11:00:39
	System	13 Oct 2020 11:00:39

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-13T07:00:32', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '6779416b-251b-4fff-ac1f-a8aae8a7ade0'	System	13 Oct 2020 11:00:39
User entered 'No (N)'	System	13 Oct 2020 11:00:39

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-13T07:00:38', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '6779416b-251b-4fff-ac1f-a8aae8a7ade0' User entered '13 Oct 2020 07:00'	System	13 Oct 2020 11:00:39
	System	13 Oct 2020 11:00:39

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '12 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:11:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '13 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 5'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-14T00:29:43', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'd64392ce-b247-4fa4-a220-d66007b59748' User entered 'None (0)'	System	14 Oct 2020 04:32:18
	System	14 Oct 2020 04:32:18

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-14T00:30:22', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'd64392ce-b247-4fa4-a220-d66007b59748' User entered 'None (0)'	System	14 Oct 2020 04:32:18
	System	14 Oct 2020 04:32:18

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-14T00:30:46', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'd64392ce-b247-4fa4-a220-d66007b59748' User entered 'None (0)'	System	14 Oct 2020 04:32:18
	System	14 Oct 2020 04:32:18

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-14T00:31:05', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'd64392ce-b247-4fa4-a220-d66007b59748' User entered 'None (0)'	System	14 Oct 2020 04:32:18
	System	14 Oct 2020 04:32:18

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-14T00:31:12', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'd64392ce-b247-4fa4-a220-d66007b59748' User entered 'None (0)'	System	14 Oct 2020 04:32:18
	System	14 Oct 2020 04:32:18

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-14T00:31:38', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'd64392ce-b247-4fa4-a220-d66007b59748' User entered 'None (0)'	System	14 Oct 2020 04:32:18
	System	14 Oct 2020 04:32:18

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-14T00:32:07', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'd64392ce-b247-4fa4-a220-d66007b59748' User entered 'No (N)'	System	14 Oct 2020 04:32:18
	System	14 Oct 2020 04:32:18

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-14T00:32:16', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'd64392ce-b247-4fa4-a220-d66007b59748' User entered '14 Oct 2020 00:32'	System	14 Oct 2020 04:32:18
	System	14 Oct 2020 04:32:18

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '13 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:11:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '14 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 6'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-14T20:10:47', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'cf771501-e605-4358-9d6d-e4d0ff16207e' User entered 'None (0)'	System	20 Oct 2020 23:53:44
	System	20 Oct 2020 23:53:44

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-14T20:10:55', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'cf771501-e605-4358-9d6d-e4d0ff16207e' User entered 'None (0)'	System	20 Oct 2020 23:53:44
	System	20 Oct 2020 23:53:44

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-14T20:11:00', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'cf771501-e605-4358-9d6d-e4d0ff16207e' User entered 'None (0)'	System	20 Oct 2020 23:53:44
	System	20 Oct 2020 23:53:44

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-14T20:11:10', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'cf771501-e605-4358-9d6d-e4d0ff16207e' User entered 'None (0)'	System	20 Oct 2020 23:53:44
	System	20 Oct 2020 23:53:44

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-14T20:11:19', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'cf771501-e605-4358-9d6d-e4d0ff16207e' User entered 'None (0)'	System	20 Oct 2020 23:53:44
	System	20 Oct 2020 23:53:44

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-14T20:11:27', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'cf771501-e605-4358-9d6d-e4d0ff16207e' User entered 'None (0)'	System	20 Oct 2020 23:53:44
	System	20 Oct 2020 23:53:44

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-14T20:12:01', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'cf771501-e605-4358-9d6d-e4d0ff16207e' User entered 'No (N)'	System	20 Oct 2020 23:53:44
	System	20 Oct 2020 23:53:44

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-14T20:12:04', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'cf771501-e605-4358-9d6d-e4d0ff16207e' User entered '14 Oct 2020 20:12'	System	20 Oct 2020 23:53:44
	System	20 Oct 2020 23:53:44

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '14 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:11:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '15 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 7'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-15T22:36:44', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'e82044db-6db9-4746-b486-d62b28f75c18' User entered 'None (0)'	System	20 Oct 2020 23:53:46
	System	20 Oct 2020 23:53:46

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-15T22:37:14', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'e82044db-6db9-4746-b486-d62b28f75c18' User entered 'None (0)'	System	20 Oct 2020 23:53:46
	System	20 Oct 2020 23:53:46

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-15T22:37:25', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'e82044db-6db9-4746-b486-d62b28f75c18' User entered 'None (0)'	System	20 Oct 2020 23:53:46
	System	20 Oct 2020 23:53:46

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-15T22:37:31', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'e82044db-6db9-4746-b486-d62b28f75c18' User entered 'None (0)'	System	20 Oct 2020 23:53:46
	System	20 Oct 2020 23:53:46

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-15T22:37:38', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'e82044db-6db9-4746-b486-d62b28f75c18' User entered 'None (0)'	System	20 Oct 2020 23:53:46
	System	20 Oct 2020 23:53:46

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-15T22:37:48', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'e82044db-6db9-4746-b486-d62b28f75c18' User entered 'None (0)'	System	20 Oct 2020 23:53:46
	System	20 Oct 2020 23:53:46

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-15T22:38:00', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'e82044db-6db9-4746-b486-d62b28f75c18' User entered 'No (N)'	System	20 Oct 2020 23:53:46
	System	20 Oct 2020 23:53:46

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2020-10-15T22:38:14', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'e82044db-6db9-4746-b486-d62b28f75c18' User entered '15 Oct 2020 22:38'	System	20 Oct 2020 23:53:46
	System	20 Oct 2020 23:53:46

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '15 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3542332

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:11:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:33:38
User entered '16 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3542332

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:54
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 19:07:06
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	21 Oct 2020 16:07:59

US3542332

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:54
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 19:07:06
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	21 Oct 2020 16:08:38
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	21 Oct 2020 16:08:38
User entered '19 Oct 2020' reason for change: Data Entry Error	Taylor Ladson (b) (4) (b) (4)	21 Oct 2020 16:08:38
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	21 Oct 2020 16:07:59
User entered '20 Oct 2020'	Taylor Ladson (b) (4) (b) (4)	21 Oct 2020 16:07:59

US3542332

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:54
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:07:06
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Taylor Ladson (b) (4)	21 Oct 2020 16:07:59

US3542332

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:54
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:07:06
User entered 'left voicemail'	(b) (4) Taylor Ladson (b) (4)	21 Oct 2020 16:07:59

US3542332

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:08
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 19:07:06
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Oct 2020 16:08:22

US3542332

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:08
User entered 'I'	System	21 Oct 2020 16:08:22

US3542332

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:54
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:06:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:03:33

US3542332

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:54
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:06:28
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:03:33

US3542332

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:54
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:06:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:03:33

US3542332

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:54
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:06:28
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:03:33

US3542332

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:08
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 02:06:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:05:24

US3542332

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:08
User entered 'l'	System	27 Oct 2020 18:05:24

US3542332

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:54
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	02 Nov 2020 18:28:25

US3542332

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:54
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered '2 Nov 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 18:28:25

US3542332

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:54
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 18:28:25

US3542332

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:54
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered empty.	(b) (4) Erika Faust (b) (4)	02 Nov 2020 18:28:25

US3542332

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:08
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 18:28:18

US3542332

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:08
User entered 'l'	System	02 Nov 2020 18:28:18

US3542332

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:11:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 17:57:00

US3542332

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:11:57

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered '12 Nov 2020'	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 17:57:00
	(b) (4)	

US3542332

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered 'Clinic (Clinic)'	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 17:57:00
	(b) (4)	

US3542332

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:11:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User entered 'VISIT2'	System	13 Nov 2020 17:57:00

US3542332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User accepted default value 'Pre-Dose (PREDOSE)'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:06:28

US3542332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Nov 2020 16:54:52
User entered 'Yes (Y)'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:06:28

US3542332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered '12 Nov 2020'	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:06:28
	(b) (4)	

US3542332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered '10:59'	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:06:28

US3542332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User entered '12 Nov 2020 10:59'	System	13 Nov 2020 18:06:28

US3542332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered '97.2' F	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:06:28
	(b) (4)	

US3542332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered 'Oral (Oral)'	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:06:28
	(b) (4)	

US3542332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:06:28
	(b) (4)	

US3542332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered '69'	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:06:28
	(b) (4)	

US3542332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User entered 'bpm'	System	13 Nov 2020 18:06:28

US3542332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered '16'	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:06:28

US3542332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User entered 'breaths/min'	System	13 Nov 2020 18:06:28

US3542332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered '126'	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:06:28
	(b) (4)	

US3542332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User entered 'mmHg'	System	13 Nov 2020 18:06:28

US3542332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered '92'	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:06:28

US3542332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User entered 'mmHg'	System	13 Nov 2020 18:06:28

US3542332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User accepted default value 'Post-Dose (POSTDOSE)'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:06:34

US3542332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:06:34
	(b) (4)	

US3542332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Nov 2020 16:54:52
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:06:34

US3542332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:06:34
	(b) (4)	

US3542332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User entered empty.	System	13 Nov 2020 18:06:34

US3542332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:06:34
	(b) (4)	

US3542332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:06:34
	(b) (4)	

US3542332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:06:34
	(b) (4)	

US3542332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:06:34
	(b) (4)	

US3542332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User entered empty.	System	13 Nov 2020 18:06:34

US3542332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Nov 2020 16:54:52
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:06:34

US3542332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User entered empty.	System	13 Nov 2020 18:06:34

US3542332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:06:34
	(b) (4)	

US3542332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User entered empty.	System	13 Nov 2020 18:06:34

US3542332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:06:34
	(b) (4)	

US3542332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User entered empty.	System	13 Nov 2020 18:06:34

US3542332

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:11:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:50
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:06:44
	(b) (4)	

US3542332

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:11:57

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:50
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered '12 Nov 2020'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:06:44

US3542332

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:11:57

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:18
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:07:33
	(b) (4)	

US3542332

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:11:57

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:18
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered 'Physician withheld dose due to Adverse DeEnna Wedding Event (PHYSICIAN AE)'	(b) (4)	(b) (4) 13 Nov 2020 18:07:33

US3542332

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:18
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered 'SAE of worsening seizure disorder ongoing.'	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:07:33

US3542332

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:11:57

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:18
User entered empty.	System	13 Nov 2020 18:07:33

US3542332

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:11:57

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:18
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:07:33

US3542332

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:18
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:07:33
	(b) (4)	

US3542332

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:18
User entered empty.	System	13 Nov 2020 18:07:33

US3542332

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:18
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:07:33
	(b) (4)	

US3542332

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:18
User entered empty.	System	13 Nov 2020 18:07:33

US3542332

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:11:57

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:18
User entered empty.	System	13 Nov 2020 18:07:33

US3542332

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:50
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:09:50
	(b) (4)	

US3542332

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:50
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered '12 Nov 2020'	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:09:50
	(b) (4)	

US3542332

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:57

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:50
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered '11:12'	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:09:50
	(b) (4)	

US3542332

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:50
User entered '12 Nov 2020 11:12'	System	13 Nov 2020 18:09:50

US3542332

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:11:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:19
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:09:57
	(b) (4)	

US3542332

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:11:57

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:19
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:09:57

US3542332

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:11:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:19
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:09:57
	(b) (4)	

US3542332

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:11:57

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:19
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:09:57
	(b) (4)	

US3542332

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:19
User entered empty.	System	13 Nov 2020 18:09:57

US3542332

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:11:57

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:19
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:09:57

US3542332

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:11:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:19
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:09:57
	(b) (4)	

US3542332

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:11:57

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:19
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:09:57

US3542332

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:11:57

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:14:19
User entered empty.	System	13 Nov 2020 18:09:57

US3542332

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:08
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:10:04
	(b) (4)	

US3542332

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:08
User entered 'I'	System	13 Nov 2020 18:10:04

US3542332

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:47:29

US3542332

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered '19 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:47:29

US3542332

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:47:29

US3542332

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:47:29

US3542332

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:08
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:47:48

US3542332

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:08
User entered 'l'	System	19 Nov 2020 16:47:48

US3542332

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:54
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:33:20
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	01 Dec 2020 20:01:08

US3542332

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:54
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:33:20
User entered '24 Nov 2020'	(b) (4) Madhu Balachandran (b) (4)	01 Dec 2020 20:01:08

US3542332

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:54
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:33:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Madhu Balachandran (b) (4)	01 Dec 2020 20:01:08

US3542332

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:54
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:33:20
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	01 Dec 2020 20:01:08

US3542332

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:08
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:33:20
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	01 Dec 2020 20:01:11

US3542332

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:08
User entered 'I'	System	01 Dec 2020 20:01:11

US3542332

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:54
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:33:20
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	04 Dec 2020 16:33:34

US3542332

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:54
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:33:20
User entered '04 Dec 2020' reason for change: New Information	(b) (4) DeEnna Wedding (b) (4)	08 Dec 2020 17:46:27
User entered '03 Dec 2020'	(b) (4) DeEnna Wedding (b) (4)	04 Dec 2020 16:33:34

US3542332

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:54
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:33:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: New Information	DeEnna Wedding (b) (4)	08 Dec 2020 17:46:27
User entered 'Contact Not Made (CONTACT NOT	(b) (4)	
MADE)'	DeEnna Wedding (b) (4)	04 Dec 2020 16:33:34
	(b) (4)	

US3542332

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:54
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:33:20
User entered empty; reason for change New Information	(b) (4)	
	DeEnna Wedding (b) (4)	08 Dec 2020 17:46:27
User entered 'PTPT UNREACHABLE left voicemail at 09:25, 10:15 and 12:18' reason for change: Data Entry Error	(b) (4)	
	DeEnna Wedding (b) (4)	04 Dec 2020 16:33:54
User entered 'ptpt unreachable'	(b) (4)	
	DeEnna Wedding (b) (4)	04 Dec 2020 16:33:34
	(b) (4)	

US3542332

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:08
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:33:20
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	04 Dec 2020 16:34:01

US3542332

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:08
User entered 'l'	System	04 Dec 2020 16:34:01

US3542332

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:11:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:39
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	14 Dec 2020 16:05:23

US3542332

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:39
User entered '14 Dec 2020'	(b) (4) Erika Faust (b) (4)	14 Dec 2020 16:05:23

US3542332

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:39
User entered 'Clinic (Clinic)'	(b) (4) Erika Faust (b) (4)	14 Dec 2020 16:05:23

US3542332

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:11:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User entered 'VISIT3'	System	14 Dec 2020 16:05:23

US3542332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:39
User entered 'No (N)'	(b) (4) Erika Faust (b) (4)	14 Dec 2020 16:06:31

US3542332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:39
User entered empty.	(b) (4) Erika Faust (b) (4)	14 Dec 2020 16:06:31

US3542332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:39
User entered empty.	(b) (4) Erika Faust (b) (4)	14 Dec 2020 16:06:31

US3542332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User entered empty.	System	14 Dec 2020 16:06:31

US3542332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:39
User entered empty.	(b) (4) Erika Faust (b) (4)	14 Dec 2020 16:06:31

US3542332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:39
User entered empty.	(b) (4) Erika Faust (b) (4)	14 Dec 2020 16:06:31

US3542332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:39
User entered empty.	(b) (4) Erika Faust (b) (4)	14 Dec 2020 16:06:31

US3542332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:39
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	14 Dec 2020 16:06:31

US3542332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User entered empty.	System	14 Dec 2020 16:06:31

US3542332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:39
User entered empty.	(b) (4) Erika Faust (b) (4)	14 Dec 2020 16:06:31

US3542332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User entered empty.	System	14 Dec 2020 16:06:31

US3542332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:39
User entered empty.	(b) (4) Erika Faust (b) (4)	14 Dec 2020 16:06:31

US3542332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User entered empty.	System	14 Dec 2020 16:06:31

US3542332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:39
User entered empty.	(b) (4) Erika Faust (b) (4)	14 Dec 2020 16:06:31

US3542332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04
User entered empty.	System	14 Dec 2020 16:06:31

US3542332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04

US3542332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:20:04

US3542332

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:11:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:50
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:39
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	14 Dec 2020 16:06:38

US3542332

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:11:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:50
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:39
User entered '14 Dec 2020'	(b) (4) Erika Faust (b) (4)	14 Dec 2020 16:06:38

US3542332

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:50
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:39
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	14 Dec 2020 16:07:04

US3542332

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:50
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:39
User entered '14 Dec 2020'	(b) (4) Erika Faust (b) (4)	14 Dec 2020 16:07:04

US3542332

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:57

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:50
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:39
User entered '09:30'	(b) (4) Erika Faust (b) (4)	14 Dec 2020 16:07:04

US3542332

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:16:50
User entered '14 Dec 2020 09:30'	System	14 Dec 2020 16:07:04

US3542332

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:08
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:21:39
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	14 Dec 2020 16:07:09

US3542332

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:08
User entered 'I'	System	14 Dec 2020 16:07:09

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[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 (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2021-01-04T06:37:30', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '450f2eda-ddb6-401e-bdf0-6a17a83bb173' User entered 'No (N)'	System	04 Jan 2021 11:37:52
	System	04 Jan 2021 11:37:52

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

Have you been exposed to someone with 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 (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2021-01-04T06:35:27', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '450f2eda-ddb6-401e-bdf0-6a17a83bb173'	System	04 Jan 2021 11:37:52
User entered 'No (N)'	System	04 Jan 2021 11:37:52

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2021-01-04T06:37:50', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '450f2eda-ddb6-401e-bdf0-6a17a83bb173' User entered '04 Jan 2021 06:37:50'	System	04 Jan 2021 11:37:52

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[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 (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2021-02-21T00:04:49', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '662e8b52-0ab9-4b80-9b46-85855b56139f' User entered 'No (N)'	System	21 Feb 2021 05:06:04
	System	21 Feb 2021 05:06:04

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

Have you been exposed to someone with 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 (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2021-02-21T00:05:09', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '662e8b52-0ab9-4b80-9b46-85855b56139f' User entered 'No (N)'	System	21 Feb 2021 05:06:04

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2021-02-21T00:05:58', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '662e8b52-0ab9-4b80-9b46-85855b56139f' User entered '21 Feb 2021 00:05:58'	System	21 Feb 2021 05:06:04
	System	21 Feb 2021 05:06:04

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[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 (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2021-03-10T02:36:13-05:00', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'a64cd3ea-ca72-41b5-b1b2-8da8abcdbf4e'	System	10 Mar 2021 07:37:10
User entered 'No (N)'	System	10 Mar 2021 07:37:10

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

Have you been exposed to someone with 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 (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2021-03-10T02:36:21-05:00', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'a64cd3ea-ca72-41b5-b1b2-8da8abcdbf4e'	System	10 Mar 2021 07:37:10
User entered 'No (N)'	System	10 Mar 2021 07:37:10

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2021-03-10T02:36:53-05:00', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'a64cd3ea-ca72-41b5-b1b2-8da8abcdbf4e' User entered '10 Mar 2021 02:36:53'	System	10 Mar 2021 07:37:10
	System	10 Mar 2021 07:37:10

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[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 (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2021-03-18T01:15:34-04:00', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '5cd112f8-4530-4378-ac96-b1ff217347b1' User entered 'No (N)'	System	18 Mar 2021 05:16:11
	System	18 Mar 2021 05:16:11

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

Have you been exposed to someone with 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 (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2021-03-18T01:15:44-04:00', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '5cd112f8-4530-4378-ac96-b1ff217347b1' User entered 'No (N)'	System	18 Mar 2021 05:16:11

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2021-03-18T01:16:06-04:00', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '5cd112f8-4530-4378-ac96-b1ff217347b1' User entered '18 Mar 2021 01:16:06'	System	18 Mar 2021 05:16:11
	System	18 Mar 2021 05:16:11

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[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 (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2021-03-22T23:24:59-04:00', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '3fe2862d-82a8-4fec-8ca6-f312cacfb80a'	System	23 Mar 2021 03:26:06
User entered 'No (N)'	System	23 Mar 2021 03:26:06

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

Have you been exposed to someone with 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 (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2021-03-22T23:25:45-04:00', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '3fe2862d-82a8-4fec-8ca6-f312cacfb80a'	System	23 Mar 2021 03:26:06
User entered 'No (N)'	System	23 Mar 2021 03:26:06

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2021-03-22T23:26:01-04:00', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '3fe2862d-82a8-4fec-8ca6-f312cacfb80a'	System	23 Mar 2021 03:26:06
User entered '22 Mar 2021 23:26:01'	System	23 Mar 2021 03:26:06

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[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 (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2021-03-30T06:23:37-04:00', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '9609f602-bf03-4f26-b049-08ca85c2bc8d'	System	30 Mar 2021 10:27:50
User entered 'No (N)'	System	30 Mar 2021 10:27:50

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

Have you been exposed to someone with 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 (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2021-03-30T06:24:05-04:00', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '9609f602-bf03-4f26-b049-08ca85c2bc8d'	System	30 Mar 2021 10:27:50
User entered 'No (N)'	System	30 Mar 2021 10:27:50

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2021-03-30T06:24:13-04:00', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '9609f602-bf03-4f26-b049-08ca85c2bc8d' User entered '30 Mar 2021 06:24:13'	System	30 Mar 2021 10:27:50
	System	30 Mar 2021 10:27:50

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[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 (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2021-04-08T13:50:57-04:00', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'ee30f78c-0908-4702-8388-11db69de28b5' User entered 'No (N)'	System	08 Apr 2021 17:51:32

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

Have you been exposed to someone with 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 (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2021-04-08T13:51:13-04:00', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'ee30f78c-0908-4702-8388-11db69de28b5'	System	08 Apr 2021 17:51:32
User entered 'No (N)'	System	08 Apr 2021 17:51:32

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2021-04-08T13:51:22-04:00', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: 'ee30f78c-0908-4702-8388-11db69de28b5' User entered '08 Apr 2021 13:51:22'	System	08 Apr 2021 17:51:32
	System	08 Apr 2021 17:51:32

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '20 Nov 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '24 Nov 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '27 Nov 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '01 Dec 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '04 Dec 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '08 Dec 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '11 Dec 2022 00:01'	System	20 Nov 2020 12:12:00

US3542332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:11:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:12:00
Amendment Manager: User entered '15 Dec 2022 23:59'	System	20 Nov 2020 12:12:00

US3542332

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:11:57

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2021-03-10T02:37:15-05:00', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '65fa2bde-5096-4a9c-9ccc-e2bb511be667'	System	10 Mar 2021 07:38:10
User entered 'No (N)'	System	10 Mar 2021 07:38:10

US3542332

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:11:57

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B27D12E6-A270-49A3-87C9-AE9E3ECB3633)', Time: '2021-03-10T02:37:50-05:00', User OID: 'PatientReportedOutcome (US3542332)', ODM File OID: '65fa2bde-5096-4a9c-9ccc-e2bb511be667'	System	10 Mar 2021 07:38:10
User entered '10 Mar 2021 02:37:50'	System	10 Mar 2021 07:38:10

US3542332

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:54
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:52:45
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	11 Jan 2021 14:25:35

US3542332

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:54
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:52:45
User entered '05 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Jan 2021 14:25:35

US3542332

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:54
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:52:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4)	11 Jan 2021 14:25:35

US3542332

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:18:54
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:52:45
User entered empty.	(b) (4) Erika Faust (b) (4)	11 Jan 2021 14:25:35

US3542332

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:08
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:52:45
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Jan 2021 14:25:39

US3542332

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:15:08
User entered 'l'	System	11 Jan 2021 14:25:39

US3542332

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:08:55
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:47:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:01:56

US3542332

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:08:55
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:47:19
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:01:56

US3542332

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:08:55
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:47:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:01:56

US3542332

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:08:55
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:47:19
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:01:56

US3542332

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:08:55
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:47:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:02:35

US3542332

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:08:55
User entered 'l'	System	11 Feb 2021 17:02:35

US3542332

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:08:55
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 22:24:18
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	10 Mar 2021 19:02:33

US3542332

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:08:55
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 22:24:18
User entered '09 Mar 2021'	(b) (4) Taylor Ladson (b) (4)	10 Mar 2021 19:02:33
	(b) (4)	

US3542332

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:08:55
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 22:24:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Taylor Ladson (b) (4)	10 Mar 2021 19:02:33

US3542332

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:08:55
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 22:24:18
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	10 Mar 2021 19:02:33

US3542332

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:08:55
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 22:24:18
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	10 Mar 2021 19:02:24
	(b) (4)	

US3542332

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:08:55
User entered 'l'	System	10 Mar 2021 19:02:24

US3542332

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	14 Apr 2021 17:59:56
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	14 Apr 2021 17:12:11

US3542332

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	14 Apr 2021 17:59:56
User entered '13 Apr 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	14 Apr 2021 17:12:11

US3542332

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	14 Apr 2021 17:59:56
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Erika Faust (b) (4) (b) (4)	14 Apr 2021 17:12:11

US3542332

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	14 Apr 2021 17:59:56
User entered 'Left voicemails at 11:23, 12:29, 12:57'	(b) (4) Erika Faust (b) (4) (b) (4)	14 Apr 2021 17:12:11

US3542332

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	14 Apr 2021 17:59:56
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	14 Apr 2021 17:12:16

US3542332

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:57

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'l'	System	14 Apr 2021 17:12:16

US3542332

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

Form: Visit Date

Generated On: 10 Jun 2021 08:11:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:44:24

US3542332

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

Form: Visit Date

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '04 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:44:24

US3542332

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

Form: Visit Date

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:44:24

US3542332

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

Form: Visit Date

Generated On: 10 Jun 2021 08:11:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered 'UNBLND_DECIDE'	System	05 Feb 2021 16:44:24

US3542332

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

Form: Unblinding

Generated On: 10 Jun 2021 08:11:57

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '04 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:48:02

US3542332

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

Form: Unblinding

Generated On: 10 Jun 2021 08:11:57

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:53:14
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:44:54

US3542332

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

Form: Unblinding

Generated On: 10 Jun 2021 08:11:57

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:48:02

US3542332

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

Form: Unblinding

Generated On: 10 Jun 2021 08:11:57

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:53:14
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:44:54

US3542332

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

Form: Unblinding

Generated On: 10 Jun 2021 08:11:57

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '04 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:48:02

US3542332

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

Form: Unblinding

Generated On: 10 Jun 2021 08:11:57

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:48:02

US3542332

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

Form: Unblinding

Generated On: 10 Jun 2021 08:11:57

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:48:02

US3542332

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

Form: Unblinding

Generated On: 10 Jun 2021 08:11:57

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Not Administered (NA)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:48:02

US3542332

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

Form: Unblinding

Generated On: 10 Jun 2021 08:11:57

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:48:02

US3542332

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

Form: Unblinding

Generated On: 10 Jun 2021 08:11:57

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered empty.	System	05 Feb 2021 16:48:02

US3542332

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

Form: Unblinding

Generated On: 10 Jun 2021 08:11:57

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered 'I'	System	05 Feb 2021 16:48:02

US3542332

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:11:57

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:58:28

US3542332

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:11:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:58:28

US3542332

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:11:57

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered empty.	System	05 Feb 2021 16:58:28
DataPoint set to visible.	System	05 Feb 2021 16:48:02

US3542332

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:11:57

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:58:28

US3542332

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:11:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:58:28

US3542332

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:11:57

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered empty.	System	05 Feb 2021 16:58:28
DataPoint set to visible.	System	05 Feb 2021 16:48:02

US3542332

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	05 Feb 2021 16:58:28

US3542332

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Feb 2021 16:58:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 16:58:42
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Feb 2021 16:58:28
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 16:58:28

US3542332

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '04 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:58:28

US3542332

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '09:46'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:58:28

US3542332

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered '04 Feb 2021 09:46'	System	05 Feb 2021 16:58:28

US3542332

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:58:28

US3542332

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:58:28

US3542332

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:58:28

US3542332

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '80'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:58:28

US3542332

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered 'bpm'	System	05 Feb 2021 16:58:28

US3542332

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '16'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:58:28

US3542332

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered 'breaths/min'	System	05 Feb 2021 16:58:28

US3542332

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '116'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:58:28

US3542332

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered 'mmHg'	System	05 Feb 2021 16:58:28

US3542332

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '82'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:58:28

US3542332

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:11:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered 'mmHg'	System	05 Feb 2021 16:58:28

US3542332

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:11:57

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:58:28

US3542332

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:11:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:58:28

US3542332

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:11:57

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered empty.	System	05 Feb 2021 16:58:28
DataPoint set to visible.	System	05 Feb 2021 16:48:02

US3542332

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	05 Feb 2021 16:59:35

US3542332

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:59:35

US3542332

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '04 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:59:35

US3542332

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '10:27'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:59:35

US3542332

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered '04 Feb 2021 10:27'	System	05 Feb 2021 16:59:35

US3542332

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '97.6' F	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:59:35

US3542332

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:59:35

US3542332

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:59:35

US3542332

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '68'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:59:35

US3542332

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered 'bpm'	System	05 Feb 2021 16:59:35

US3542332

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '16'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:59:35

US3542332

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered 'breaths/min'	System	05 Feb 2021 16:59:35

US3542332

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '120'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:59:35

US3542332

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered 'mmHg'	System	05 Feb 2021 16:59:35

US3542332

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '83'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:59:35

US3542332

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:11:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered 'mmHg'	System	05 Feb 2021 16:59:35

US3542332

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

Form: Physical Examination

Generated On: 10 Jun 2021 08:11:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:59:51

US3542332

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

Form: Physical Examination

Generated On: 10 Jun 2021 08:11:57

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '04 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:59:51

US3542332

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

Form: Exposure

Generated On: 10 Jun 2021 08:11:57

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:00:10

US3542332

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

Form: Exposure

Generated On: 10 Jun 2021 08:11:57

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:00:10

US3542332

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

Form: Exposure

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:00:10

US3542332

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

Form: Exposure

Generated On: 10 Jun 2021 08:11:57

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered 'mRNA-1273'	System	05 Feb 2021 17:00:10
DataPoint set to visible.	System	05 Feb 2021 16:48:02

US3542332

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

Form: Exposure

Generated On: 10 Jun 2021 08:11:57

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '04 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:00:10

US3542332

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

Form: Exposure

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '09:57'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:00:10

US3542332

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

Form: Exposure

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered '04 Feb 2021 09:57'	System	05 Feb 2021 17:00:10

US3542332

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

Form: Exposure

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:00:10

US3542332

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

Form: Exposure

Generated On: 10 Jun 2021 08:11:57

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered 'ONCE'	System	05 Feb 2021 17:00:10

US3542332

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

Form: Exposure

Generated On: 10 Jun 2021 08:11:57

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered 'INTRAMUSCULAR'	System	05 Feb 2021 17:00:10

US3542332

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:00:56

US3542332

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '04 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:00:56

US3542332

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:57

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '09:54'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:00:56

US3542332

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered '04 Feb 2021 09:54'	System	05 Feb 2021 17:00:56

US3542332

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:11:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:01:08

US3542332

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:11:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '04 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:01:08

US3542332

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:11:57

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '09:52'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:01:08

US3542332

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered '04 Feb 2021 09:52'	System	05 Feb 2021 17:01:08

US3542332

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

Form: Continuing

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:01:13

US3542332

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

Form: Continuing

Generated On: 10 Jun 2021 08:11:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:47:30
User entered 'I'	System	05 Feb 2021 17:01:13

US3542332

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:48:20
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 15:03:57
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Feb 2021 21:15:19

US3542332

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:48:20
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 15:03:57
User entered '11 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Feb 2021 21:15:19

US3542332

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:48:20
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 15:03:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4)	25 Feb 2021 21:15:19

US3542332

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:11:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:48:20
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 15:03:57
User entered empty.	(b) (4) Erika Faust (b) (4)	25 Feb 2021 21:15:19

US3542332

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:48:20
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 15:03:57
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Feb 2021 21:15:24

US3542332

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:48:20
User entered 'l'	System	25 Feb 2021 21:15:24

US3542332

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:11:57

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:48:20
User entered 'I'	System	25 Feb 2021 21:15:24
DataPoint set to visible.	System	25 Feb 2021 21:15:24

US3542332

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:11:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:16
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:43:46
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Erika Faust (b) (4)	05 Mar 2021 17:33:26
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:22:34

US3542332

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:16
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:43:46
User entered '05 Mar 2021' reason for change: Data Entry Error	(b) (4)	
	Erika Faust (b) (4)	05 Mar 2021 17:33:26
User entered empty.	(b) (4)	
	Erika Faust (b) (4)	05 Mar 2021 17:22:34
	(b) (4)	

US3542332

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:16
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:43:46
User entered 'Clinic (Clinic)' reason for change:	(b) (4)	
Data Entry Error	Erika Faust (b) (4)	05 Mar 2021 17:33:26
User entered empty.	(b) (4)	
	Erika Faust (b) (4)	05 Mar 2021 17:22:34
	(b) (4)	

US3542332

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:11:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:16
User entered 'OLD29'	System	05 Mar 2021 17:22:34

US3542332

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:16
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:43:46
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Erika Faust (b) (4)	05 Mar 2021 17:34:25
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:22:47

US3542332

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:16
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:43:46
User entered '05 Mar 2021' reason for change: Data Entry Error	(b) (4)	
	Erika Faust (b) (4)	05 Mar 2021 17:34:25
User entered empty.	(b) (4)	
	Erika Faust (b) (4)	05 Mar 2021 17:22:47
	(b) (4)	

US3542332

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:16
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:43:46
User entered '08:15' reason for change: Data Entry Error	(b) (4) Erika Faust (b) (4)	05 Mar 2021 17:34:25
User entered empty.	Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:22:47

US3542332

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:16
User entered '05 Mar 2021 08:15'	System	05 Mar 2021 17:34:25
User entered empty.	System	05 Mar 2021 17:22:47

US3542332

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:16
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:43:46
User entered '98.6' F reason for change: Data Entry Error	(b) (4) Erika Faust (b) (4)	05 Mar 2021 17:34:25
User entered empty.	Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:22:47

US3542332

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:16
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:43:46
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
	Erika Faust (b) (4)	05 Mar 2021 17:34:25
User entered empty.	(b) (4)	
	Erika Faust (b) (4)	05 Mar 2021 17:22:47
	(b) (4)	

US3542332

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:16
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:43:46
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:22:47

US3542332

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:16
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:43:46
User entered '80' reason for change: Data Entry Error	(b) (4) Erika Faust (b) (4)	05 Mar 2021 17:34:25
User entered empty.	Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:22:47

US3542332

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:16
User entered 'bpm'	System	05 Mar 2021 17:34:25
User entered empty.	System	05 Mar 2021 17:22:47

US3542332

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:16
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:43:46
User entered '16' reason for change: Data Entry Error	(b) (4) Erika Faust (b) (4)	05 Mar 2021 17:34:25
User entered empty.	Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:22:47

US3542332

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:16
User entered 'breaths/min'	System	05 Mar 2021 17:34:25
User entered empty.	System	05 Mar 2021 17:22:47

US3542332

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:16
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:43:46
User entered '138' reason for change: Data Entry Error	(b) (4) Erika Faust (b) (4)	05 Mar 2021 17:34:25
User entered empty.	Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:22:47

US3542332

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:16
User entered 'mmHg'	System	05 Mar 2021 17:34:25
User entered empty.	System	05 Mar 2021 17:22:47

US3542332

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:16
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:43:46
User entered '94' reason for change: Data Entry Error	(b) (4) Erika Faust (b) (4)	05 Mar 2021 17:34:25
User entered empty.	Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:22:47

US3542332

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:16
User entered 'mmHg'	System	05 Mar 2021 17:34:25
User entered empty.	System	05 Mar 2021 17:22:47

US3542332

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:16

US3542332

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:11:57

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:16

US3542332

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:11:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:16
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:43:46
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Erika Faust (b) (4)	05 Mar 2021 17:34:38
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:22:52

US3542332

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:11:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:16
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:43:46
User entered '05 Mar 2021' reason for change: Data Entry Error	(b) (4)	
	Erika Faust (b) (4)	05 Mar 2021 17:34:38
User entered empty.	(b) (4)	
	Erika Faust (b) (4)	05 Mar 2021 17:22:52
	(b) (4)	

US3542332

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:16
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:43:46
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Erika Faust (b) (4)	05 Mar 2021 17:35:03
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:22:56

US3542332

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:16
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 05MAR2021 is recorded under Participant Decision Visit / OL-D29 in EDC, however the same is reported under OL-3 D57 visit in PPD Central lab. Please reconcile the correct Visit and confirm in query response. Else clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 08:38:07
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 05MAR2021 is recorded under Participant Decision Visit / OL-D29 in EDC, however the same is reported under OL-3 D57 visit in PPD Central lab. Please reconcile the correct Visit and confirm in query response. Else clarify, Thank you' answered with 'The correct visit code is OL-D29. Site processing lab is contacting GCL to address this.' (Site from DM).	Hannah Yellin (b) (4) (b) (4)	18 Mar 2021 18:37:41
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 05MAR2021 is recorded under Participant Decision Visit / OL-D29 in EDC, however the same is reported under OL-3 D57 visit in PPD Central lab. Please reconcile the correct Visit and confirm in query response. Else clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 07:42:41
User signature succeeded.	David Diemert (b) (4) (b) (4)	06 Mar 2021 00:43:46
User entered '05 Mar 2021' reason for change: Data Entry Error	Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:35:03
User entered empty.	Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:22:56

US3542332

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:57

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:16
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:43:46
User entered '08:16' reason for change: Data Entry Error	(b) (4) Erika Faust (b) (4)	05 Mar 2021 17:35:03
User entered empty.	Erika Faust (b) (4) (b) (4)	05 Mar 2021 17:22:56

US3542332

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:16
User entered '05 Mar 2021 08:16'	System	05 Mar 2021 17:35:03
User entered empty.	System	05 Mar 2021 17:22:56

US3542332

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:11:57

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:48:13
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:54:17
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered 'Yes (Y)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	09 Nov 2020 17:39:12

US3542332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:57

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:25:07
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:21
User entered 'USA-US084-2020-mRNA-1273-P301000004'	System	10 Nov 2020 22:08:11
User entered 'New'	(b) (4), (b) (6)	10 Nov 2020 22:08:11

US3542332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:57

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:54:42
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User coded data point as SOC: Nervous system disorders, HLGT: Seizures (incl subtypes), HLT: Seizures and seizure disorders NEC, PT: Seizure, LLT: Seizure - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 03:56:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 03:56:42
Data point term sent to Coder	System	09 Nov 2020 17:42:16
User entered 'Exacerbation of seizure disorder'	Caroline Thoreson (b) (4)	09 Nov 2020 17:42:14

US3542332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 21:33:00
Query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' answered with 'Yes, they were hospitalized overnight' (Site from Safety).	Elissa Malkin (b) (4) (b) (4)	24 Nov 2020 15:34:27
User opened query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 18:30:59
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:54:45
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 22:32:01
User entered 'Yes (Y)'	Caroline Thoreson (b) (4) (b) (4)	09 Nov 2020 17:42:14

US3542332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:54:47
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	09 Nov 2020 17:42:14

US3542332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:54:49
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	09 Nov 2020 17:42:14

US3542332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:54:51
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered '7 Nov 2020'	(b) (4) Caroline Thoreson (b) (4)	09 Nov 2020 17:42:14

US3542332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:57

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:54:53
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	09 Nov 2020 17:42:14

US3542332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 17:42:14

US3542332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:57

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:54:58
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	09 Nov 2020 17:42:14

US3542332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:57:41
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
DataPoint Un-verified.	(b) (4)	
	Elissa Malkin (b) (4)	24 Dec 2020 14:19:02
Signature has been broken.	(b) (4)	
	Elissa Malkin (b) (4)	24 Dec 2020 14:19:02
User entered '09 Nov 2020' reason for change: New Information	(b) (4)	
	Elissa Malkin (b) (4)	24 Dec 2020 14:19:02
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:55:01
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
	(b) (4)	
User entered '8 Nov 2020'	Caroline Thoreson (b) (4)	09 Nov 2020 17:42:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:57

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:55:03
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	09 Nov 2020 17:42:14

US3542332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 17:42:14

US3542332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:57

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:55:04
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Caroline Thoreson (b) (4)	09 Nov 2020 17:42:14

US3542332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:55:06
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered 'Yes (Y)'	(b) (4) Caroline Thoreson (b) (4)	09 Nov 2020 17:42:14

US3542332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:57

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	09 Nov 2020 17:42:14

US3542332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:57

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	09 Nov 2020 17:42:14

US3542332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 17:55:19
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:55:15
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered 'I'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	09 Nov 2020 17:42:14

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered '7 Nov 2020'	(b) (4) Caroline Thoreson (b) (4)	09 Nov 2020 17:42:14

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered '8 Nov 2020'	(b) (4) Caroline Thoreson (b) (4)	09 Nov 2020 17:42:14

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Folder: Adverse Events

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	09 Nov 2020 17:42:14

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	09 Nov 2020 17:42:14

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	09 Nov 2020 17:42:14

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	09 Nov 2020 17:42:14

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	09 Nov 2020 17:42:14

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:55:27
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered 'Not Related (NOT RELATED)'	(b) (4) Caroline Thoreson (b) (4)	09 Nov 2020 17:42:14

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Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:55:28
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered 'Not Related (NOT RELATED)'	(b) (4) Caroline Thoreson (b) (4)	09 Nov 2020 17:42:14

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Form: Adverse Events (1)

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Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:58:50
User closed query 'Per CDM: As "EXACERBATION OF SEIZURE DISORDER" is the reason for dosing discontinuation, Please consider to update Action taken with investigational product to "Investigational product withdrawn". Thank you.' (Site from DM). Query 'Per CDM: As "EXACERBATION OF SEIZURE DISORDER" is the reason for dosing discontinuation, Please consider to update Action taken with investigational product to "Investigational product withdrawn". Thank you.' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 20:06:28
DataPoint Un-verified.	Elissa Malkin (b) (4)	19 Nov 2020 18:12:49
Signature has been broken.	(b) (4) Elissa Malkin (b) (4)	19 Nov 2020 18:12:37
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Per Query Resolution	Elissa Malkin (b) (4)	19 Nov 2020 18:12:37
User opened query 'Per CDM: As "EXACERBATION OF SEIZURE DISORDER" is the reason for dosing discontinuation, Please consider to update Action taken with investigational product to "Investigational product withdrawn". Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 10:00:09
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:55:30
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	09 Nov 2020 17:42:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 17:42:45
User entered 'None (NONE)' reason for change: Data Entry Error	Caroline Thoreson (b) (4)	09 Nov 2020 17:42:45
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4) System	09 Nov 2020 17:42:14
User entered empty.	Caroline Thoreson (b) (4)	09 Nov 2020 17:42:14

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:55:37
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	09 Nov 2020 17:42:14

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Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:55:33
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered 'l'	(b) (4) Caroline Thoreson (b) (4)	09 Nov 2020 17:42:14

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:58:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:55:35
Signature has been broken.	DeEnna Wedding (b) (4)	13 Nov 2020 18:22:49
User entered '0' reason for change: Data Entry Error	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:22:49
User signature succeeded.	(b) (4) David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered '1'	(b) (4) Caroline Thoreson (b) (4)	09 Nov 2020 17:42:14
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:55:39
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Caroline Thoreson (b) (4)	09 Nov 2020 17:42:14

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:55:41
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	09 Nov 2020 17:42:14

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User closed query 'Per DM CLR RQ: Thanks for the response. Please update the Concomitant procedures eCRF accordingly if applicable. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 08:00:23
Query 'Per DM CLR RQ: Thanks for the response. Please update the Concomitant procedures eCRF accordingly if applicable. ' answered with 'CT head was already added to Con Procedures eCRF.' (Site from DM).	David Diemert (b) (4) (b) (4)	10 Mar 2021 17:19:10
User opened query 'Per DM CLR RQ: Thanks for the response. Please update the Concomitant procedures eCRF accordingly if applicable. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 06:20:15
User closed query 'Per DM CLR: SAE Narrative = ADMITTED FOR FURTHER WORK-UP. However, please confirm what are these "WORK-UP" and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 06:20:15
User signature succeeded.	David Diemert (b) (4) (b) (4)	09 Mar 2021 04:13:25
Query 'Per DM CLR: SAE Narrative = ADMITTED FOR FURTHER WORK-UP. However, please confirm what are these "WORK-UP" and ensure that this is captured in the appropriate eCRF. ' answered with 'Work up consisted of labs and CT head, the results of which are already reported in the Narrative. This has been clarified.' (Site from DM).	David Diemert (b) (4) (b) (4)	08 Mar 2021 14:44:26
Signature has been broken.	David Diemert (b) (4) (b) (4)	08 Mar 2021 14:43:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:11:57

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PT WITH PMH OF SEIZURE DISORDER REPORTS THAT HE HAD 4 WITNESSED SEIZURES ON 7-NOV-2020. NO HEAD INJURY BUT STATES HE WAS POST-ICTAL AND DOES NOT RECALL ALL EVENTS OF SEIZURE. HE WAS SEEN AT LOCAL HOSPITAL AND ADMITTED FOR FURTHER WORK-UP (CT head and labs) AND MANAGEMENT. HE REPORTS COMPLIANCE WITH MEDICATIONS; LAST SEIZURE WAS IN JUNE 2020. LAB RESULTS FROM 07NOV2020: SODIUM 141; POTASSIUM 4.1; GLUCOSE 211; CALCIUM 9.6; HEMOGLOBIN 13.7; WBC 10.5; ETHANOL <10.0. CT OF HEAD FROM 07NOV2020: NO ACUTE INTRACRANIAL PATHOLOGY.' reason for change: Per Query Resolution	David Diemert (b) (4)	08 Mar 2021 14:43:46
User opened query 'Per DM CLR: SAE Narrative = ADMITTED FOR FURTHER WORK-UP. However, please confirm what are these "WORK-UP" and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	26 Dec 2020 21:36:46
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:58:50
User closed query 'PV Query: Please provide results of lab test (sodium, potassium, glucose, calcium, ect), if available.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 21:33:26
User closed query 'PV Query: Please provide type of seizure the subject experienced (i.e. grand mal, partial (focal), absence, myoclonic, etc)' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 21:33:20
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 21:33:10
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 21:32:44

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EAB) (1725)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'records faxed' (Site from Safety).	Elissa Malkin (b) (4)	24 Nov 2020 17:58:12
Query 'PV Query: Please provide results of lab test (sodium, potassium, glucose, calcium, ect), if available.' answered with 'provided in narrative' (Site from Safety).	Elissa Malkin (b) (4)	24 Nov 2020 15:41:36
DataPoint Un-verified.	Elissa Malkin (b) (4)	24 Nov 2020 15:41:27
Signature has been broken.	Elissa Malkin (b) (4)	24 Nov 2020 15:41:27
User entered 'PT WITH PMH OF SEIZURE DISORDER REPORTS THAT HE HAD 4 WITNESSED SEIZURES ON 7-NOV-2020. NO HEAD INJURY BUT STATES HE WAS POST-ICTAL AND DOES NOT RECALL ALL EVENTS OF SEIZURE. HE WAS SEEN AT LOCAL HOSPITAL AND ADMITTED FOR FURTHER WORK-UP AND MANAGEMENT. HE REPORTS COMPLIANCE WITH MEDICATIONS; LAST SEIZURE WAS IN JUNE 2020.	Elissa Malkin (b) (4)	24 Nov 2020 15:41:27
Lab results from 07NOV2020: Sodium 141; Potassium 4.1; Glucose 211; Calcium 9.6; Hemoglobin 13.7; WBC 10.5; Ethanol <10.0. CT of head from 07NOV2020: no acute intracranial pathology.' reason for change: Per Query Resolution		
Query 'PV Query: Please provide type of seizure the subject experienced (i.e. grand mal, partial (focal), absence, myoclonic, etc)' answered with 'not provided in medical records' (Site from Safety).	Elissa Malkin (b) (4)	24 Nov 2020 15:38:07
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so' answered with 'COVID-19 testing performed 07NOV2020 (RNA test) - result not provided. Participant would have been informed if test was positive.' (Site from Safety).	Elissa Malkin (b) (4)	24 Nov 2020 15:37:08

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide results of lab test (sodium, potassium, glucose, calcium, ect), if available.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 18:31:41
User opened query 'PV Query: Please provide type of seizure the subject experienced (i.e. grand mal, partial (focal), absence, myoclonic, etc)' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 18:31:29
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 18:31:10
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 18:30:24
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:02:49
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered 'Pt with PMH of seizure disorder reports that he had 4 witnessed seizures on 7-NOV-2020. No head injury but states he was post-ictal and does not recall all events of seizure. He was seen at local hospital and admitted for further work-up and management. He reports compliance with medications; last seizure was in June 2020.'	(b) (4) Caroline Thoreson (b) (4)	09 Nov 2020 17:42:14

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 17:42:14

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Folder: Adverse Events

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 17:42:14

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Nov 2020 17:42:14

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Folder: Adverse Events

Form: Adverse Events (2)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User coded data point as SOC: Nervous system disorders, HLGT: Seizures (incl subtypes), HLT: Seizures and seizure disorders NEC, PT: Seizure, LLT: Seizure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 06:10:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 06:10:52
User closed query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Seizure Disorder. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 10:38:33
User signature succeeded.	David Diemert (b) (4) (b) (4)	09 Mar 2021 04:13:25
Data point term sent to Coder	System	08 Mar 2021 14:40:37
Query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Seizure Disorder. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' answered with 'Clarified' (Site from DM).	David Diemert (b) (4) (b) (4)	08 Mar 2021 14:40:20
Coding entries removed.	David Diemert (b) (4) (b) (4)	08 Mar 2021 14:40:08
User entered 'Worsened SEIZURE disorder' reason for change: Per Query Resolution	David Diemert (b) (4) (b) (4)	08 Mar 2021 14:40:08
User opened query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Seizure Disorder. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 17:25:10
User coded data point as SOC: Nervous system disorders, HLGT: Seizures (incl subtypes), HLT: Seizures and seizure disorders NEC, PT: Seizure, LLT: Breakthrough seizure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Feb 2021 17:17:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Feb 2021 17:17:46
Data point term sent to Coder	System	05 Feb 2021 17:16:48

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Breakthrough Seizure'	(b) (4), (b) (6)	05 Feb 2021 17:16:21

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Folder: Adverse Events

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:16:21

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:16:21

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:16:21

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:16:21

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[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:16:21

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44
User entered empty.	System	05 Feb 2021 17:16:21

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:16:21

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:16:21

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:16:21

US3542332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44
User entered empty.	System	05 Feb 2021 17:16:21

US3542332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:57

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:16:21

US3542332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:16:21

US3542332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:57

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:16:21

US3542332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:57

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:16:21

US3542332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:16:21

US3542332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:57

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:16:21

US3542332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:57

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:16:21

US3542332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:16:21

US3542332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:16:21

US3542332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:16:21

US3542332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:16:21

US3542332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:57

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:16:21

US3542332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:16:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:16:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:57

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:16:21

US3542332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:57

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:16:21

US3542332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered 'l'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:16:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:16:21

US3542332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:57

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:16:21

US3542332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:57

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:16:21

US3542332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:57

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:16:21

US3542332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:57

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44
User entered '0'	System	05 Feb 2021 17:16:21

US3542332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:57

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44
User entered 'I'	System	05 Feb 2021 17:16:21

US3542332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:11:57

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:44

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Dizziness, LLT: Dizziness - version MedDRA\\23.0.	Coder Import (b) (4)	08 Mar 2021 18:53:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Mar 2021 18:53:00
Data point term sent to Coder	System	08 Mar 2021 18:51:22
User entered 'Dizziness'	(b) (4), (b) (6)	08 Mar 2021 18:51:19

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:19

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:19

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:19

US3542332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:19

US3542332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:19

US3542332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46
User entered empty.	System	08 Mar 2021 18:51:19

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:19

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:19

US3542332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:19

US3542332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46
User entered empty.	System	08 Mar 2021 18:51:19

US3542332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:19

US3542332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:19

US3542332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:19

US3542332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:19

US3542332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:19

US3542332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:19

US3542332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:19

US3542332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:19

US3542332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:19

US3542332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:19

US3542332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:19

US3542332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:19

US3542332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:19

US3542332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:19

US3542332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:19

US3542332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered 'l'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:19

US3542332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:19

US3542332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:19

US3542332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:19

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:19

US3542332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:58:08
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:19

US3542332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46
User entered '0'	System	08 Mar 2021 18:51:19

US3542332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46
User entered 'I'	System	08 Mar 2021 18:51:19

US3542332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:11:57

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:46

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 13:21:56
User entered 'USA-US084-2020-mRNA-1273-P301000004'	(b) (4), (b) (6)	30 Apr 2021 13:21:48

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:28
User coded data point as SOC: Nervous system disorders, HLGT: Seizures (incl subtypes), HLT: Seizures and seizure disorders NEC, PT: Seizure, LLT: Seizure - version MedDRA\23.0.	Coder Import (b) (4)	30 Apr 2021 08:27:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	30 Apr 2021 08:27:25
Data point term sent to Coder	System	29 Apr 2021 18:51:36
User entered 'Worsening of seizure disorder'	Caroline Thoreson (b) (4)	29 Apr 2021 18:51:13

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:28
User entered 'Yes (Y)'	(b) (4) Caroline Thoreson (b) (4)	29 Apr 2021 18:51:13

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:28
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	29 Apr 2021 18:51:13

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:28
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	29 Apr 2021 18:51:13

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:28
User entered '12 Apr 2021'	(b) (4) Caroline Thoreson (b) (4)	29 Apr 2021 18:51:13

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:28
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	29 Apr 2021 18:51:13

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 18:51:13

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:28
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	29 Apr 2021 18:51:13

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:28
User entered '13 Apr 2021'	(b) (4) Caroline Thoreson (b) (4)	29 Apr 2021 18:51:13

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:28
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	29 Apr 2021 18:51:13

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 18:51:13

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:28
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Caroline Thoreson (b) (4)	29 Apr 2021 18:51:13

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:28
User entered 'Yes (Y)'	(b) (4) Caroline Thoreson (b) (4)	29 Apr 2021 18:51:13

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:28
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	29 Apr 2021 18:51:13

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:28
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	29 Apr 2021 18:51:13

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:28
User entered 'I'	(b) (4) Caroline Thoreson (b) (4)	29 Apr 2021 18:51:13

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:28
User entered '12 Apr 2021'	(b) (4) Caroline Thoreson (b) (4)	29 Apr 2021 18:51:13

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:28
User entered '13 Apr 2021'	(b) (4) Caroline Thoreson (b) (4)	29 Apr 2021 18:51:13

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:28
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	29 Apr 2021 18:51:13

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:28
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	29 Apr 2021 18:51:13

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:28
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	29 Apr 2021 18:51:13

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:28
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	29 Apr 2021 18:51:13

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:28
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	29 Apr 2021 18:51:13

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:28
User entered 'Not Related (NOT RELATED)'	(b) (4) Caroline Thoreson (b) (4)	29 Apr 2021 18:51:13

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:28
User entered 'Not Related (NOT RELATED)'	(b) (4) Caroline Thoreson (b) (4)	29 Apr 2021 18:51:13

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:28
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Caroline Thoreson (b) (4)	29 Apr 2021 18:51:13

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

None

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:28
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	29 Apr 2021 18:51:13

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:28
User entered 'I'	(b) (4) Caroline Thoreson (b) (4)	29 Apr 2021 18:51:13

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:28
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	29 Apr 2021 18:51:13

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Caroline Thoreson (b) (4)	29 Apr 2021 18:51:13

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:28
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	29 Apr 2021 18:51:13

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:28
User entered 'Participant was hospitalized on 12-13-APR-2021 for seizure. He experienced breakthrough seizure on 12-APR-2021 due to non-compliance with Keppra.'	(b) (4) Caroline Thoreson (b) (4)	29 Apr 2021 18:51:13

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 18:51:13

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 18:51:13

US3542332

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:11:57

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Apr 2021 18:51:13

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:11:57

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:48:13
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:19:46
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:18:25

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:57

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Oct 2020 17:21:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 17:21:18
Data point term sent to Coder	System	12 Oct 2020 17:20:17
User entered 'gabapentin'	DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:19:39

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:57

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:19:39

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:57

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'seizure disorder'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:19:39

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:57

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '300'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:19:39

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:57

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'mg (mg)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:19:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:57

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:19:39
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:57

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'three times daily (TID)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:19:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:19:39
	(b) (4)	

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:57

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Oral (ORAL)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:19:39
	(b) (4)	

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:57

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:19:39

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'UN UNK 2014'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:19:39

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '0'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:19:39

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:57

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:19:39

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:19:39

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:19:39

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	12 Oct 2020 17:19:39

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Oct 2020 17:19:39

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Oct 2020 17:19:39

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:18:55
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: LEVETIRACETAM, PRODUCTSYNONYM: KEPPRA - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Oct 2020 17:22:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 17:22:20
Data point term sent to Coder	System	12 Oct 2020 17:21:20
User entered 'keppra'	DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:20:34

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:18:55
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:20:34

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:18:55
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'seizure disorder'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:20:34

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:18:55
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '1500'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:20:34

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:18:55
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'mg (mg)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:20:34

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:18:55
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:20:34

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:18:55
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'once daily (QD)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:20:34

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:18:55
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:20:34

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:18:55
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Oral (ORAL)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:20:34

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:18:55
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:20:34

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:18:55
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'UN UNK 2014'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:20:34

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:18:55
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '0'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:20:34

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:18:55
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:05:20
Signature has been broken.	(b) (4), (b) (6)	05 Feb 2021 17:05:20
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	05 Feb 2021 17:05:20
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:20:34

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:18:55
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:05:20
Signature has been broken.	(b) (4), (b) (6)	05 Feb 2021 17:05:20
User entered '06 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	05 Feb 2021 17:05:20
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:20:34

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:18:55
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:20:34

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:18:55
User entered 'I'	System	12 Oct 2020 17:20:34

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:18:55
User entered 'I'	System	12 Oct 2020 17:20:34

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:18:55
User entered '804 (804)'	System	12 Oct 2020 17:20:34

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:57

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: ZONISAMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Oct 2020 17:44:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 17:44:29
Data point term sent to Coder	System	12 Oct 2020 17:22:22
User entered 'zonisamide'	DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:21:45

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:57

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:21:45

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:57

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'seizure disorder'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:21:45

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:57

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '100'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:21:45

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:57

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'mg (mg)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:21:45

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:57

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:21:45
	(b) (4)	

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:57

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'other (OTHER)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:21:45

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'five times per day'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:21:45

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:57

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Oral (ORAL)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:21:45

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:57

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:21:45

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'UN Feb 2020'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:21:45

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '0'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:21:45

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:57

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:21:45

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:21:45

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:21:45

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 17:21:45

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 17:21:45

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 17:21:45

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:57

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Oct 2020 17:24:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 17:24:29
Data point term sent to Coder	System	12 Oct 2020 17:23:24
User entered 'lisinopril'	DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:22:27

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:57

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:22:27

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:57

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'hypertension'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:22:27

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:57

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '40'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:22:27

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:57

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'mg (mg)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:22:27

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:57

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:22:27

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:57

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'once daily (QD)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:22:27

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:22:27

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:57

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Oral (ORAL)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:22:27

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:57

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:22:27

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'UN UNK 2014'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:22:27

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '0'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:22:27

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:57

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:22:27

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:22:27

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:22:27

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	12 Oct 2020 17:22:27

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Oct 2020 17:22:27

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Oct 2020 17:22:27

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:57

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Oct 2020 17:24:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 17:24:29
Data point term sent to Coder	System	12 Oct 2020 17:23:24
User entered 'simvastatin'	DeEnna Wedding (b) (4) (b) (4)	12 Oct 2020 17:23:09

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:57

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:23:09

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:57

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'high cholesterol'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:23:09

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:57

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '40'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:23:09

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:57

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'mg (mg)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:23:09

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:57

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:23:09
	(b) (4)	

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:57

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'once daily (QD)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:23:09

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:23:09

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:57

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Oral (ORAL)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:23:09

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:57

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:23:09

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'UN UNK 2018'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:23:09

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '0'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:23:09

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:57

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:23:09

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:23:09

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:23:09

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 17:23:09

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Oct 2020 17:23:09

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Oct 2020 17:23:09

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:57

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 17:25:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 17:25:17
Data point term sent to Coder	System	12 Oct 2020 17:24:26
User entered 'aspirin'	DeEnna Wedding (b) (4)	12 Oct 2020 17:24:05

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:57

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:24:05

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:57

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'stroke prevention'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:24:05

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:57

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '325'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:24:05

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:57

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'mg (mg)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:24:05

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:57

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:24:05

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:57

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'three times daily (TID)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:24:05

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:24:05

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:57

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Oral (ORAL)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:24:05

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:57

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:24:05

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'UN UNK 2018'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:24:05

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered '0'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:24:05

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:57

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:24:05

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:24:05

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 13:16:28
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	12 Oct 2020 17:24:05

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	12 Oct 2020 17:24:05

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	12 Oct 2020 17:24:05

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Oct 2020 17:24:05

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: CARBOXAMIDE DERIVATIVES, PRODUCT: CARBAMAZEPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 18:20:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 18:20:47
Data point term sent to Coder	System	13 Nov 2020 18:19:59
User entered 'carbamazepine'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:19:12

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered 'No (N)'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:19:12

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered 'seizure disorder'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:19:12

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:57

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered '400'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:19:12

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered 'mg (mg)'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:19:12

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:19:12

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered 'three times daily (TID)'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:19:12

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:57

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:19:12

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:57

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered 'Oral (ORAL)'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:19:12

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:19:12

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered '08 Nov 2020'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:19:12

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered '0'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:19:12

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:57

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 06:56:27
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'participant has a medical history of seizure disorder and requires this medication daily' (Site from DM).	Elissa Malkin (b) (4) (b) (4)	23 Dec 2020 14:45:50
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 19:02:20
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered 'Yes (Y)'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:19:12

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:19:12

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered 'No (N)'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:19:12

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	13 Nov 2020 18:19:12

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Nov 2020 18:19:12

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Nov 2020 18:19:12

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 18:20:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 18:20:47
Data point term sent to Coder	System	13 Nov 2020 18:19:59
User entered 'eliquis'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:19:52

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered 'Yes (Y)'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:19:52

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered 'stroke prevention'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:19:52

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:57

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered '2.5'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:19:52

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered 'mg (mg)'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:19:52

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:19:52

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered 'once daily (QD)'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:19:52

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:57

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:19:52

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:57

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered 'Oral (ORAL)'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:19:52

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:19:52

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered 'UN Jan 2020'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:19:52

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered '0'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:19:52

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered 'Yes (Y)'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:19:52

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:19:52

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered 'No (N)'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:19:52

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	13 Nov 2020 18:19:52

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Nov 2020 18:19:52

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Nov 2020 18:19:52

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: LEVETIRACETAM, PRODUCTSYNONYM: KEPPRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 15:16:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 15:16:43
Data point term sent to Coder	System	05 Jan 2021 15:15:14
Coding entries removed.	Erika Faust (b) (4)	05 Jan 2021 15:15:09
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: LEVETIRACETAM, PRODUCTSYNONYM: KEPPRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 18:21:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 18:21:48
Data point term sent to Coder	System	13 Nov 2020 18:21:00
User entered 'keppra'	DeEnna Wedding (b) (4)	13 Nov 2020 18:20:41
	(b) (4)	

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:16
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered 'No (N)'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:20:41

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:16
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:52:45
DataPoint Un-verified.	(b) (4)	
	Erika Faust (b) (4)	05 Jan 2021 15:15:09
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	05 Jan 2021 15:15:09
User entered 'WORSENING SEIZURE DISORDER	(b) (4)	
(Loading dose)' reason for change: New Information	Erika Faust (b) (4)	05 Jan 2021 15:15:09
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered 'worsening seizure disorder'	DeEnna Wedding (b) (4)	13 Nov 2020 18:20:41
	(b) (4)	

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:16
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered '1.5'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:20:41

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:16
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered 'g (g)'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:20:41

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:16
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:20:41

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:16
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered 'once (ONCE)'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:20:41

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:16
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:20:41

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:16
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered 'Intravenous (INTRAVENOUS)'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:20:41

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:16
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:20:41

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:16
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered '07 Nov 2020'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:20:41

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:16
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered '0'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:20:41

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:16
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered 'No (N)'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:20:41

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:16
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered '07 Nov 2020'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:20:41

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:16
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered 'No (N)'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:20:41

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:16
User entered empty.	System	13 Nov 2020 18:20:41

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:16
User entered empty.	System	13 Nov 2020 18:20:41

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:16
User entered empty.	System	13 Nov 2020 18:20:41

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:26
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: CARBOXAMIDE DERIVATIVES, PRODUCT: CARBAMAZEPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:54:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:54:50
Data point term sent to Coder	System	13 Nov 2020 18:22:01
User entered 'cabamazepine'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:21:18

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:26
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered 'No (N)'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:21:18

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:26
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered 'worsening seizure disorder'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:21:18

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:26
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered '400'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:21:18

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:26
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered 'mg (mg)'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:21:18

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:26
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:21:18

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:26
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered 'once (ONCE)'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:21:18

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:26
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:21:18

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:26
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered 'Oral (ORAL)'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:21:18

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:26
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:21:18

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:26
User closed query 'Per DM CLR: Indication of Worsening Seizure Disorder was noted. However, the corresponding AE does not match the dates of this medication. Please review and update applicable details as appropriate. Otherwise, clarify.	(b) (4), (b) (6)	29 Dec 2020 03:27:35
' (Site from DM). Query 'Per DM CLR: Indication of Worsening Seizure Disorder was noted. However, the corresponding AE does not match the dates of this medication. Please review and update applicable details as appropriate. Otherwise, clarify.	Elissa Malkin (b) (4) (b) (4)	24 Dec 2020 14:18:31
' answered with 'AE reviewed and end date is 09NOV20202 - this was a loading dose of medication' (Site from DM). User opened query 'Per DM CLR: Indication of Worsening Seizure Disorder was noted. However, the corresponding AE does not match the dates of this medication. Please review and update applicable details as appropriate. Otherwise, clarify.	(b) (4), (b) (6)	18 Dec 2020 19:02:47
' (Site from DM). User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered '09 Nov 2020'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:21:18

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:26
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered '0'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:21:18

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:26
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered 'No (N)'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:21:18

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:26
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered '09 Nov 2020'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:21:18

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:26
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:58:02
User entered 'No (N)'	DeEnna Wedding (b) (4) (b) (4)	13 Nov 2020 18:21:18

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:26
User entered empty.	System	13 Nov 2020 18:21:18

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:26
User entered empty.	System	13 Nov 2020 18:21:18

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:26
User entered empty.	System	13 Nov 2020 18:21:18

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:11:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:32
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:33:20
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Dec 2020 20:03:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Dec 2020 20:03:56
Data point term sent to Coder	System	01 Dec 2020 20:03:21
User entered 'influenza vaccine'	DeEnna Wedding (b) (4)	01 Dec 2020 20:02:56

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:11:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:32
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:33:20
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	01 Dec 2020 20:02:56

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:11:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:32
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:33:20
User entered 'influenza prevention'	(b) (4) DeEnna Wedding (b) (4)	01 Dec 2020 20:02:56

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:11:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:32
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:33:20
User entered '0.5'	(b) (4) DeEnna Wedding (b) (4)	01 Dec 2020 20:02:56

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:11:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:32
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:33:20
User entered 'mL (mL)'	(b) (4) DeEnna Wedding (b) (4)	01 Dec 2020 20:02:56

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:11:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:32
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:33:20
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	01 Dec 2020 20:02:56

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:11:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:32
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:33:20
User entered 'once (ONCE)'	(b) (4) DeEnna Wedding (b) (4)	01 Dec 2020 20:02:56

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:11:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:32
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:33:20
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	01 Dec 2020 20:02:56

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:11:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:32
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:33:20
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) DeEnna Wedding (b) (4)	01 Dec 2020 20:02:56

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:11:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:32
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:33:20
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	01 Dec 2020 20:02:56

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:11:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:32
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:33:20
User entered '04 Nov 2020'	(b) (4) DeEnna Wedding (b) (4)	01 Dec 2020 20:02:56

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:11:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:32
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:33:20
User entered '0'	(b) (4) DeEnna Wedding (b) (4)	01 Dec 2020 20:02:56

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:11:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:32
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:33:20
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	01 Dec 2020 20:02:56

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:11:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:32
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:33:20
User entered '04 Nov 2020'	(b) (4) DeEnna Wedding (b) (4)	01 Dec 2020 20:02:56

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:11:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:32
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:33:20
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	01 Dec 2020 20:02:56

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:11:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:32
User entered empty.	System	01 Dec 2020 20:02:56

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:32
User entered empty.	System	01 Dec 2020 20:02:56

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:32
User entered empty.	System	01 Dec 2020 20:02:56

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:11:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:26
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM, PRODUCTSYNONYM: ATIVAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Feb 2021 19:12:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Feb 2021 19:12:46
Data point term sent to Coder	System	05 Feb 2021 17:07:40
User entered 'Ativan'	(b) (4), (b) (6)	05 Feb 2021 17:07:16

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:11:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:26
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:07:16

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:11:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:26
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Worsening Seizure Disorder'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:07:16

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:11:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:26
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'l'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:07:16

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:11:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:26
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:07:16

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:11:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:26
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:07:16

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:11:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:26
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:07:16

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:11:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:26
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:07:16

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:11:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:26
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:07:16

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:11:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:26
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:07:16

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:11:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:26
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '07 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:07:16

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:11:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:26
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:07:16

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:11:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:26
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:07:16

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:11:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:26
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '07 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:07:16

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:11:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:26
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:07:16

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:11:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:26
User entered empty.	System	05 Feb 2021 17:07:16

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:26
User entered empty.	System	05 Feb 2021 17:07:16

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:26
User entered empty.	System	05 Feb 2021 17:07:16

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:11:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:02
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Feb 2021 17:10:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Feb 2021 17:10:43
Data point term sent to Coder	System	05 Feb 2021 17:09:41
User entered 'Tylenol'	(b) (4), (b) (6)	05 Feb 2021 17:09:01

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:11:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:02
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:09:01

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:11:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:02
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Right Hand Osteoarthritis'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:09:01

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:11:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:02
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '500'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:09:01

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:11:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:02
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:09:01

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:11:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:02
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:09:01

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:11:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:02
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:09:01

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:11:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:02
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Every 6 hours as needed'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:09:01

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:11:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:02
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:09:01

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:11:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:02
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:09:01

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:11:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:02
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening RIGHT HAND OSTEOARTHRITIS should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 10:55:56
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening RIGHT HAND OSTEOARTHRITIS should be recorded, and update con med indication or provide clarification. ' answered with 'RIGHT HAND OSTEOARTHRITIS was not worsening. This med was prescribed as PRN while he was in hospital based on his past medical history of RIGHT HAND OSTEOARTHRITIS.' (Site from DM).	David Diemert (b) (4) (b) (4)	15 Mar 2021 16:27:06
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening RIGHT HAND OSTEOARTHRITIS should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 15:44:30
User signature succeeded.	David Diemert (b) (4) (b) (4)	08 Feb 2021 01:55:42
User entered '07 Nov 2020'	(b) (4), (b) (6)	05 Feb 2021 17:09:01

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:11:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:02
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:09:01

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:11:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:02
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:09:01

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:11:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:02
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '09 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:09:01

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:11:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:02
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:09:01

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:11:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:02
User entered empty.	System	05 Feb 2021 17:09:01

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:02
User entered empty.	System	05 Feb 2021 17:09:01

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:02
User entered empty.	System	05 Feb 2021 17:09:01

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:11:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:19
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Feb 2021 17:11:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Feb 2021 17:11:57
Data point term sent to Coder	System	05 Feb 2021 17:10:42
User entered 'Multivitamin'	(b) (4), (b) (6)	05 Feb 2021 17:10:14

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:11:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:19
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:10:14

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:11:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:19
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Health Maintenance'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:10:14

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:11:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:19
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Unknown'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:10:14

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:11:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:19
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:10:14

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:11:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:19
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Unknown'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:10:14

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:11:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:19
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:10:14

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:11:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:19
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:10:14

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:11:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:19
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:10:14

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:11:57

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:19
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:10:14

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:11:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:19
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '07 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:10:14

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:11:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:19
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:10:14

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:11:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:19
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:10:14

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:11:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:19
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '09 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:10:14

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:11:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:19
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:10:14

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:11:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:19
User entered 'I'	System	05 Feb 2021 17:10:14

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:19
User entered 'I'	System	05 Feb 2021 17:10:14

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:19
User entered '804 (804)'	System	05 Feb 2021 17:10:14

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:11:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:08
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: LEVETIRACETAM, PRODUCTSYNONYM: KEPPRA - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Feb 2021 17:12:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Feb 2021 17:12:44
Data point term sent to Coder	System	05 Feb 2021 17:11:45
User entered 'Keppra'	(b) (4), (b) (6)	05 Feb 2021 17:11:33

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:11:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:08
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:11:33

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:11:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:08
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Seizure Disorder'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:11:33

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:11:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:08
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '1500'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:11:33

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:11:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:08
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:11:33

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:11:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:08
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:11:33

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:11:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:08
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:11:33

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:11:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:08
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:11:33

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:11:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:08
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:11:33

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:11:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:08
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:11:33

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:11:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:08
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '07 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:11:33

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:11:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:08
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:11:33

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:11:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:08
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:11:33

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:11:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:08
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '09 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:11:33

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:11:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:08
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:11:33

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:11:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:08
User entered '2'	System	05 Feb 2021 17:11:33

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:08
User entered 'I'	System	05 Feb 2021 17:11:33

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:22:08
User entered '804 (804)'	System	05 Feb 2021 17:11:33

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:11:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Feb 2021 19:39:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 19:39:49
Data point term sent to Coder	System	05 Feb 2021 17:12:46
User entered 'Ibuprofen'	(b) (4), (b) (6)	05 Feb 2021 17:12:44

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:11:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:12:44

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:11:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Right Hand Osteoarthritis'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:12:44

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:11:57

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '800'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:12:44

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:11:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:12:44

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:11:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:12:44

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:11:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:12:44

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:11:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Three Times a day as needed'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:12:44

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:11:57

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:12:44

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:11:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:12:44

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:11:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening RIGHT HAND OSTEOARTHRITIS should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 10:56:11
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening RIGHT HAND OSTEOARTHRITIS should be recorded, and update con med indication or provide clarification. ' answered with 'Not worsening RIGHT HAND OSTEOARTHRITIS. This medication was prescribed PRN while he was in hospital due to past medical history of RIGHT HAND OSTEOARTHRITIS.' (Site from DM).	David Diemert (b) (4) (b) (4)	15 Mar 2021 16:27:46
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening RIGHT HAND OSTEOARTHRITIS should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 15:44:44
User signature succeeded.	David Diemert (b) (4) (b) (4)	08 Feb 2021 01:55:42
User entered '09 Nov 2020'	(b) (4), (b) (6)	05 Feb 2021 17:12:44

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:11:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:12:44

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:11:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:12:44

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:11:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:12:44

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:11:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:12:44

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:11:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 17:12:44

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 17:12:44

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 17:12:44

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:11:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: LEVETIRACETAM, PRODUCTSYNONYM: KEPPRA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Feb 2021 17:14:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Feb 2021 17:14:45
Data point term sent to Coder	System	05 Feb 2021 17:13:47
User entered 'Keppra'	(b) (4), (b) (6)	05 Feb 2021 17:13:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:11:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:13:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:11:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Seizure Disorder'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:13:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:11:57

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '2500'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:13:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:11:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:13:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:11:57

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:13:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:11:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'once daily (QD)'	(b) (4) (D) (4), (b) (6)	05 Feb 2021 17:13:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:11:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:13:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:11:57

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:13:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:11:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:13:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:11:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '09 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:13:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:11:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:13:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:11:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:13:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:11:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:13:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:11:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:13:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:11:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	05 Feb 2021 17:13:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Feb 2021 17:13:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Feb 2021 17:13:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:11:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: LEVETIRACETAM, PRODUCTSYNONYM: KEPPRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Feb 2021 10:02:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Feb 2021 10:02:53
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
Data point term sent to Coder System	(b) (4)	05 Feb 2021 17:14:47
User entered 'Kepra (loading dose)'	(b) (4), (b) (6)	05 Feb 2021 17:14:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:11:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:46
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:14:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:11:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:46
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Breakthrough Seizure'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:14:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:11:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:46
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Unknown'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:14:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:11:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:46
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:14:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:11:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:46
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Unknown'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:14:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:11:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:46
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:14:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:11:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:46
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:14:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:11:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:46
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:14:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:11:57

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:46
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:14:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:11:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:46
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:14:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:11:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:46
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:14:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:11:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:46
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:14:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:11:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:46
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:14:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:11:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:46
User signature succeeded.	David Diemert (b) (4)	08 Feb 2021 01:55:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:14:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:11:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:46
User entered empty.	System	05 Feb 2021 17:14:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:46
User entered empty.	System	05 Feb 2021 17:14:40

US3542332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:11:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:21:46
User entered empty.	System	05 Feb 2021 17:14:40

US3542332

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:11:57

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:48:13
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
Signature has been broken.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:36
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	08 Mar 2021 18:51:36
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:46:17
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Feb 2021 14:58:28

US3542332

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:11:57

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:55

US3542332

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:11:57

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered 'CT Head'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:55

US3542332

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:11:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:55

US3542332

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:11:57

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:13:25
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:55

US3542332

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:11:57

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:30:16
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered '12 Nov 2020'	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:09:09
	(b) (4)	

US3542332

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:11:57

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:30:16
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
User entered 'SAE (specify) (SAE)'	(b) (4) DeEnna Wedding (b) (4)	13 Nov 2020 18:09:09
	(b) (4)	

US3542332

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:11:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:30:16
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:33:20
User closed query 'Per CDM: please record the record line number per CCGs (i.e. AE#1 or SAE#1, etc.) instead of AEID number' (Site from DM).	(b) (4)	
Query 'Per CDM: please record the record line number per CCGs (i.e. AE#1 or SAE#1, etc.) instead of AEID number' answered with 'Record line number recorded' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 05:11:03
Signature has been broken.	Hannah Yellin (b) (4)	01 Dec 2020 20:54:08
	(b) (4)	
User entered 'SAE #1' reason for change: Per Query Resolution	Hannah Yellin (b) (4)	01 Dec 2020 20:54:01
User opened query 'Per CDM: please record the record line number per CCGs (i.e. AE#1 or SAE#1, etc.) instead of AEID number' (Site from DM).	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	23 Nov 2020 01:49:27
User closed query 'Per CDM: Please record SAE record number instead of details ' (Site from DM).	David Diemert (b) (4)	21 Nov 2020 16:54:52
Query 'Per CDM: Please record SAE record number instead of details ' answered with 'SAE record number recorded' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 06:47:06
User entered 'SAEID	Hannah Yellin (b) (4)	18 Nov 2020 16:34:37
USA-US084-2020-MRNA-1273-P301000004'	(b) (4)	
reason for change: Per Query Resolution	Hannah Yellin (b) (4)	18 Nov 2020 16:34:29
User opened query 'Per CDM: Please record SAE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:14:00
User entered 'worsening seizure disorder'	DeEnna Wedding (b) (4)	13 Nov 2020 18:09:09
	(b) (4)	

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'USA-US084-2020-MRNA-1273-P301000004'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'Yes (Y)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'Yes (Y)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'David'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'Diemert'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered '2300 Eye Street NW'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'Washington'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 18:05:15
User signature succeeded.	David Diemert (b) (4)	30 Dec 2020 17:31:16
Un-reviewed for Safety.	(b) (4)	28 Dec 2020 16:55:40
DataPoint Un-verified.	System	28 Dec 2020 16:55:40
Signature has been broken.	System	28 Dec 2020 16:55:40
User entered empty.	System	28 Dec 2020 16:55:40
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'DC'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered '20037'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:14:36
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered 'US'	(b) (4) System	10 Nov 2020 22:08:41

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Apr 2021 13:22:21
User entered '6'	System	09 Mar 2021 18:04:59
User signature succeeded.	David Diemert (b) (4)	30 Dec 2020 17:31:16
	(b) (4)	
Signature has been broken.	System	28 Dec 2020 16:55:40
User entered '5'	System	28 Dec 2020 16:55:40
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:58:50
	(b) (4)	
Signature has been broken.	System	25 Nov 2020 21:33:54
User entered '4'	System	25 Nov 2020 21:33:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
	(b) (4)	
User entered '3'	System	20 Nov 2020 14:42:37
Signature has been broken.	System	16 Nov 2020 14:14:47
User entered '2'	System	16 Nov 2020 14:14:47
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
	(b) (4)	
User entered '1'	System	10 Nov 2020 22:08:41

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'USA-US084-2020-MRNA-1273-P301000004'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'Yes (Y)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'Yes (Y)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'David'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'Diemert'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered '2300 Eye Street NW'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'Washington'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 18:05:15
User signature succeeded.	David Diemert (b) (4)	30 Dec 2020 17:31:16
Un-reviewed for Safety.	(b) (4)	28 Dec 2020 16:55:40
DataPoint Un-verified.	System	28 Dec 2020 16:55:40
Signature has been broken.	System	28 Dec 2020 16:55:40
User entered empty.	System	28 Dec 2020 16:55:40
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'DC'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered '20037'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:14:36
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered 'US'	(b) (4) System	10 Nov 2020 22:08:41

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Apr 2021 13:22:21
User entered '6'	System	09 Mar 2021 18:04:59
User signature succeeded.	David Diemert (b) (4)	30 Dec 2020 17:31:16
	(b) (4)	
Signature has been broken.	System	28 Dec 2020 16:55:40
User entered '5'	System	28 Dec 2020 16:55:40
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:58:50
	(b) (4)	
Signature has been broken.	System	25 Nov 2020 21:33:54
User entered '4'	System	25 Nov 2020 21:33:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
	(b) (4)	
User entered '3'	System	20 Nov 2020 14:42:37
Signature has been broken.	System	16 Nov 2020 14:14:47
User entered '2'	System	16 Nov 2020 14:14:47
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
	(b) (4)	
User entered '1'	System	10 Nov 2020 22:08:41

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:11:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered '10/Nov/2020 22:08'	(b) (4) System	10 Nov 2020 22:08:41

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:11:57

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)	20 Nov 2020 21:01:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:14:36
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered 'l'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:41

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'USA-US084-2020-MRNA-1273-P301000004'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'Yes (Y)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'Yes (Y)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

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[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'David'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'Diemert'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

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[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered '2300 Eye Street NW'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'Washington'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 18:05:15
User signature succeeded.	David Diemert (b) (4)	30 Dec 2020 17:31:16
Un-reviewed for Safety.	(b) (4)	28 Dec 2020 16:55:40
DataPoint Un-verified.	System	28 Dec 2020 16:55:40
Signature has been broken.	System	28 Dec 2020 16:55:40
User entered empty.	System	28 Dec 2020 16:55:40
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'DC'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered '20037'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:14:36
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered 'US'	(b) (4) System	10 Nov 2020 22:08:41

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Apr 2021 13:22:21
User entered '6'	System	09 Mar 2021 18:04:59
User signature succeeded.	David Diemert (b) (4)	30 Dec 2020 17:31:16
	(b) (4)	
Signature has been broken.	System	28 Dec 2020 16:55:40
User entered '5'	System	28 Dec 2020 16:55:40
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:58:50
	(b) (4)	
Signature has been broken.	System	25 Nov 2020 21:33:54
User entered '4'	System	25 Nov 2020 21:33:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
	(b) (4)	
User entered '3'	System	20 Nov 2020 14:42:37
Signature has been broken.	System	16 Nov 2020 14:14:47
User entered '2'	System	16 Nov 2020 14:14:47
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
	(b) (4)	
User entered '1'	System	10 Nov 2020 22:08:41

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:11:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:01:31
User entered '16/Nov/2020 09:14'	System	16 Nov 2020 14:14:47

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:11:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:01:31
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:42:22
User entered 'l'	(b) (4), (b) (6)	16 Nov 2020 14:14:47

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'USA-US084-2020-MRNA-1273-P301000004'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'Yes (Y)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'Yes (Y)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'David'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'Diemert'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered '2300 Eye Street NW'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'Washington'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 18:05:15
User signature succeeded.	David Diemert (b) (4)	30 Dec 2020 17:31:16
Un-reviewed for Safety.	(b) (4)	28 Dec 2020 16:55:40
DataPoint Un-verified.	System	28 Dec 2020 16:55:40
Signature has been broken.	System	28 Dec 2020 16:55:40
User entered empty.	System	28 Dec 2020 16:55:40
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'DC'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered '20037'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:14:36
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered 'US'	(b) (4) System	10 Nov 2020 22:08:41

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Apr 2021 13:22:21
User entered '6'	System	09 Mar 2021 18:04:59
User signature succeeded.	David Diemert (b) (4)	30 Dec 2020 17:31:16
	(b) (4)	
Signature has been broken.	System	28 Dec 2020 16:55:40
User entered '5'	System	28 Dec 2020 16:55:40
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:58:50
	(b) (4)	
Signature has been broken.	System	25 Nov 2020 21:33:54
User entered '4'	System	25 Nov 2020 21:33:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
	(b) (4)	
User entered '3'	System	20 Nov 2020 14:42:37
Signature has been broken.	System	16 Nov 2020 14:14:47
User entered '2'	System	16 Nov 2020 14:14:47
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
	(b) (4)	
User entered '1'	System	10 Nov 2020 22:08:41

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:11:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:01:31
User entered '20/Nov/2020 09:42'	System	20 Nov 2020 14:42:37

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:11:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:33:42
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:01:31
User entered 'l'	(b) (4), (b) (6)	20 Nov 2020 14:42:37

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'USA-US084-2020-MRNA-1273-P301000004'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'Yes (Y)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'Yes (Y)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'David'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'Diemert'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered '2300 Eye Street NW'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'Washington'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 18:05:15
User signature succeeded.	David Diemert (b) (4)	30 Dec 2020 17:31:16
Un-reviewed for Safety.	(b) (4)	28 Dec 2020 16:55:40
DataPoint Un-verified.	System	28 Dec 2020 16:55:40
Signature has been broken.	System	28 Dec 2020 16:55:40
User entered empty.	System	28 Dec 2020 16:55:40
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'DC'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered '20037'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:14:36
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered 'US'	(b) (4) System	10 Nov 2020 22:08:41

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Apr 2021 13:22:21
User entered '6'	System	09 Mar 2021 18:04:59
User signature succeeded.	David Diemert (b) (4)	30 Dec 2020 17:31:16
	(b) (4)	
Signature has been broken.	System	28 Dec 2020 16:55:40
User entered '5'	System	28 Dec 2020 16:55:40
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:58:50
	(b) (4)	
Signature has been broken.	System	25 Nov 2020 21:33:54
User entered '4'	System	25 Nov 2020 21:33:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
	(b) (4)	
User entered '3'	System	20 Nov 2020 14:42:37
Signature has been broken.	System	16 Nov 2020 14:14:47
User entered '2'	System	16 Nov 2020 14:14:47
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
	(b) (4)	
User entered '1'	System	10 Nov 2020 22:08:41

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:11:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:58:50
User entered '25/Nov/2020 16:33'	(b) (4) System	25 Nov 2020 21:33:54

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:11:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 16:55:29
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:58:50
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 21:33:54

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'USA-US084-2020-MRNA-1273-P301000004'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'Yes (Y)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'Yes (Y)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'David'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'Diemert'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered '2300 Eye Street NW'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'Washington'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 18:05:15
User signature succeeded.	David Diemert (b) (4)	30 Dec 2020 17:31:16
Un-reviewed for Safety.	(b) (4)	28 Dec 2020 16:55:40
DataPoint Un-verified.	System	28 Dec 2020 16:55:40
Signature has been broken.	System	28 Dec 2020 16:55:40
User entered empty.	System	28 Dec 2020 16:55:40
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'DC'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered '20037'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:14:36
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered 'US'	(b) (4) System	10 Nov 2020 22:08:41

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Apr 2021 13:22:21
User entered '6'	System	09 Mar 2021 18:04:59
User signature succeeded.	David Diemert (b) (4)	30 Dec 2020 17:31:16
	(b) (4)	
Signature has been broken.	System	28 Dec 2020 16:55:40
User entered '5'	System	28 Dec 2020 16:55:40
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:58:50
	(b) (4)	
Signature has been broken.	System	25 Nov 2020 21:33:54
User entered '4'	System	25 Nov 2020 21:33:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
	(b) (4)	
User entered '3'	System	20 Nov 2020 14:42:37
Signature has been broken.	System	16 Nov 2020 14:14:47
User entered '2'	System	16 Nov 2020 14:14:47
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
	(b) (4)	
User entered '1'	System	10 Nov 2020 22:08:41

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:11:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Dec 2020 17:31:16
User entered '28/Dec/2020 08:55'	(b) (4) System	28 Dec 2020 16:55:40

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:11:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 18:05:15
User signature succeeded.	David Diemert (b) (4)	30 Dec 2020 17:31:16
User entered 'I'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 16:55:40

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'USA-US084-2020-MRNA-1273-P301000004'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'Yes (Y)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'Yes (Y)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'David'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'Diemert'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered '2300 Eye Street NW'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'Washington'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 18:05:15
User signature succeeded.	David Diemert (b) (4)	30 Dec 2020 17:31:16
Un-reviewed for Safety.	(b) (4)	28 Dec 2020 16:55:40
DataPoint Un-verified.	System	28 Dec 2020 16:55:40
Signature has been broken.	System	28 Dec 2020 16:55:40
User entered empty.	System	28 Dec 2020 16:55:40
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'DC'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered '20037'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:14:36
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered 'US'	(b) (4) System	10 Nov 2020 22:08:41

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Apr 2021 13:22:21
User entered '6'	System	09 Mar 2021 18:04:59
User signature succeeded.	David Diemert (b) (4)	30 Dec 2020 17:31:16
	(b) (4)	
Signature has been broken.	System	28 Dec 2020 16:55:40
User entered '5'	System	28 Dec 2020 16:55:40
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:58:50
	(b) (4)	
Signature has been broken.	System	25 Nov 2020 21:33:54
User entered '4'	System	25 Nov 2020 21:33:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
	(b) (4)	
User entered '3'	System	20 Nov 2020 14:42:37
Signature has been broken.	System	16 Nov 2020 14:14:47
User entered '2'	System	16 Nov 2020 14:14:47
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
	(b) (4)	
User entered '1'	System	10 Nov 2020 22:08:41

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:11:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:14:17
User entered '09/Mar/2021 13:04'	(b) (4) System	09 Mar 2021 18:04:59

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:11:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:14:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:05:15
User entered 'I'	(b) (4), (b) (6)	09 Mar 2021 18:04:59

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'USA-US084-2020-MRNA-1273-P301000004'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'Yes (Y)'	System	10 Nov 2020 22:08:11

US3542332

Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'Yes (Y)'	System	10 Nov 2020 22:08:11

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'No (N)'	System	10 Nov 2020 22:08:11

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[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'David'	System	10 Nov 2020 22:08:11

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'Diemert'	System	10 Nov 2020 22:08:11

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[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered '2300 Eye Street NW'	System	10 Nov 2020 22:08:11

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[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'Washington'	System	10 Nov 2020 22:08:11

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Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 18:05:15
User signature succeeded.	David Diemert (b) (4)	30 Dec 2020 17:31:16
Un-reviewed for Safety.	(b) (4)	28 Dec 2020 16:55:40
DataPoint Un-verified.	System	28 Dec 2020 16:55:40
Signature has been broken.	System	28 Dec 2020 16:55:40
User entered empty.	System	28 Dec 2020 16:55:40
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered 'DC'	System	10 Nov 2020 22:08:11

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Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:11:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:08:35
User entered '20037'	System	10 Nov 2020 22:08:11

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[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:14:36
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
User entered 'US'	(b) (4) System	10 Nov 2020 22:08:41

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Apr 2021 13:22:21
User entered '6'	System	09 Mar 2021 18:04:59
User signature succeeded.	David Diemert (b) (4)	30 Dec 2020 17:31:16
	(b) (4)	
Signature has been broken.	System	28 Dec 2020 16:55:40
User entered '5'	System	28 Dec 2020 16:55:40
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:58:50
	(b) (4)	
Signature has been broken.	System	25 Nov 2020 21:33:54
User entered '4'	System	25 Nov 2020 21:33:54
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:54:52
	(b) (4)	
User entered '3'	System	20 Nov 2020 14:42:37
Signature has been broken.	System	16 Nov 2020 14:14:47
User entered '2'	System	16 Nov 2020 14:14:47
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 22:32:01
	(b) (4)	
User entered '1'	System	10 Nov 2020 22:08:41

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Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 08:11:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:28
User entered '30/Apr/2021 06:22'	(b) (4) System	30 Apr 2021 13:22:21

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Folder: SAE USA-US084-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

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Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Apr 2021 14:24:28
User entered 'I'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 13:22:21