

US3542168 (Prod: George Washington University)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:08:13

All time stamps listed in this document are displayed in GMT

US3542168

Form: Participant Creation

Data signed: (b) (4) 05 Sep 2020 21:50:51

Generated On: 10 Jun 2021 08:08:13

Participant ID

US3542168

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

US3542168

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Sep 2020 21:50:51

Generated On: 10 Jun 2021 08:08:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3542168

Folder: Screening

Form: Demographics

Data signed: (b) (4) 24 Sep 2020 11:50:07

Generated On: 10 Jun 2021 08:08:13

Date of Birth (MMM yyyy)	(b) (6) 1966
Age	54
Age Units	YEARS
Age (Derived)	54
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) 05 Sep 2020 21:50:51

Generated On: 10 Jun 2021 08:08:13

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 05 Sep 2020 21:50:51

Generated On: 10 Jun 2021 08:08:13

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 24 Sep 2020 11:50:07

Generated On: 10 Jun 2021 08:08:13

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 01 Oct 2020 04:09:17

Generated On: 10 Jun 2021 08:08:13

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 01 Oct 2020 04:09:17

Generated On: 10 Jun 2021 08:08:13

Condition	SKIN GRAFTS FOR BURN
Start date (dd MMM yyyy)	UN UNK 1992
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 UNK 1992
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	JAN 1992
Stop Year (derived)	1992

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 01 Oct 2020 04:09:17

Generated On: 10 Jun 2021 08:08:13

Condition	GENERALIZED ANXIETY DISORDER
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

US3542168

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 01 Oct 2020 04:09:17

Generated On: 10 Jun 2021 08:08:13

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3542168

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 01 Oct 2020 04:09:17

Generated On: 10 Jun 2021 08:08:13

Condition	PTSD
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3542168

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 01 Oct 2020 04:09:17

Generated On: 10 Jun 2021 08:08:13

Condition	BORDERLINE PERSONALITY DISORDER
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 01 Oct 2020 04:09:17

Generated On: 10 Jun 2021 08:08:13

Condition	SICKLE CELL DISEASE
Start date (dd MMM yyyy)	UN (b) (6) 1966
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)	(b) (6) 1966
Start Year (derived)	1966
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3542168

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 01 Oct 2020 04:09:17

Generated On: 10 Jun 2021 08:08:13

Condition	ANXIETY DISORDER
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3542168

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 24 Sep 2020 11:50:07

Generated On: 10 Jun 2021 08:08:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 SEP 2020
Time of assessment (00:00-23:59)	15:38 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 15:38
Height (xxx.x)	68 in
Weight (xxx.x)	145 lb
BMI (xxx.x)	22.09327 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) 13 Jan 2021 03:45:28

Generated On: 10 Jun 2021 08:08:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 SEP 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) 24 Sep 2020 11:50:07

Generated On: 10 Jun 2021 08:08:13

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) 24 Sep 2020 11:50:07

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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)	False
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)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 05 Sep 2020 21:50:51

Generated On: 10 Jun 2021 08:08:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 24 Sep 2020 11:50:07

Generated On: 10 Jun 2021 08:08:13

What was the date of randomization? (dd MMM yyyy) 04 SEP 2020

What was the participant's randomization number? 111966

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) 24 Sep 2020 11:50:07

Generated On: 10 Jun 2021 08:08:13

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) 24 Sep 2020 11:50:07

Generated On: 10 Jun 2021 08:08:13

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)	04 SEP 2020
Time of assessment (00:00-23:59)	15:38 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 15:38
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Sep 2020 11:50:07

Generated On: 10 Jun 2021 08:08:13

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)	04 SEP 2020
Time of assessment (00:00-23:59)	16:48 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 16:48
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Jan 2021 03:45:28

Generated On: 10 Jun 2021 08:08:13

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) 19 Feb 2021 17:25:52

Generated On: 10 Jun 2021 08:08:13

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) 04 SEP 2020

What was the treatment time? (00:00-23:59) 16:18 (24 HR)

Treatment Date and Time (derived) 04 SEP 2020 16:18

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) 24 Sep 2020 11:50:07

Generated On: 10 Jun 2021 08:08:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 SEP 2020
Collection time (00:00-23:59)	15:56 (24 HR)
Collection date and time (derived)	04 SEP 2020 15:56

US3542168

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 24 Sep 2020 11:50:07

Generated On: 10 Jun 2021 08:08:13

Collection date (dd MMM yyyy)			04 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:58	04 SEP 2020 15:58
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 17 Sep 2020 04:28:58

Generated On: 10 Jun 2021 08:08:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:13

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

98.8 °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

04 SEP 2020 16:52

PC Open Date & Time

04 SEP 2020 16:38

PC Close Date & Time

04 SEP 2020 19:08

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.3 °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	04 SEP 2020 20:12
PC Open Date & Time	04 SEP 2020 20:03
PC Close Date & Time	05 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 13:03

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:13

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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 17:00

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:13

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 13:21

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 13:25

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 12:08

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 20:30

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:13

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

04 SEP 2020 16:53

PC Open Date & Time

04 SEP 2020 16:38

PC Close Date & Time

04 SEP 2020 19:08

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:13

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

04 SEP 2020 20:12

PC Open Date & Time

04 SEP 2020 20:03

PC Close Date & Time

05 SEP 2020 11:59

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 13:03

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:13

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

06 SEP 2020 17:01

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:13

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

07 SEP 2020 13:21

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:13

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

08 SEP 2020 13:26

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:13

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

09 SEP 2020 12:08

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:13

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

10 SEP 2020 20:31

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:13

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 ☐

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:13

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 16:55
PC Open Date & Time	04 SEP 2020 16:38
PC Close Date & Time	04 SEP 2020 19:08

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:13

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 ☐

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:13

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 20:13
PC Open Date & Time	04 SEP 2020 20:03
PC Close Date & Time	05 SEP 2020 11:59

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:13

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 ☒

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:13

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 13:04
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

51 of 2120

EAB) (1725)

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:13

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 17:02
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:13

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)

53 of 2120

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:13

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 13:22
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:13

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

55 of 2120

EAB) (1725)

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:13

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 13:26
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:13

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

57 of 2120

EAB) (1725)

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:13

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 12:08
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:13

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

59 of 2120

EAB) (1725)

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:13

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 20:31
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3542168

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Sep 2020 04:28:58

Generated On: 10 Jun 2021 08:08:13

Was Contact Attempted? Yes ☒ No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 SEP 2020

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

Comments CALLED 5 TIMES IN 2 DAYS.
UNABLE TO LEAVE
VOICEMAIL.
If Contact Not Made, please provide Comments

US3542168

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 17 Sep 2020 04:28:58

Generated On: 10 Jun 2021 08:08:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542168

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 03 Nov 2020 21:24:13

Generated On: 10 Jun 2021 08:08:13

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3542168

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 01 Oct 2020 04:09:17

Generated On: 10 Jun 2021 08:08:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542168

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 01 Oct 2020 04:09:17

Generated On: 10 Jun 2021 08:08:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542168

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Oct 2020 04:17:01

Generated On: 10 Jun 2021 08:08:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542168

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Oct 2020 04:17:01

Generated On: 10 Jun 2021 08:08:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3542168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Oct 2020 04:17:01

Generated On: 10 Jun 2021 08:08:13

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)	8 OCT 2020
Time of assessment (00:00-23:59)	10:47 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 10:47
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3542168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Oct 2020 04:17:01

Generated On: 10 Jun 2021 08:08:13

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	

US3542168

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Oct 2020 04:17:01

Generated On: 10 Jun 2021 08:08:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 OCT 2020

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

US3542168

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Oct 2020 04:17:01

Generated On: 10 Jun 2021 08:08:13

Was study treatment given? Yes ☐
No ☒

If No, reason not given

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

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

What was the study treatment?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3542168

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Oct 2020 04:17:01

Generated On: 10 Jun 2021 08:08:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 OCT 2020
Collection time (00:00-23:59)	11:40 (24 HR)
Collection date and time (derived)	8 OCT 2020 11:40

US3542168

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Oct 2020 04:17:01

Generated On: 10 Jun 2021 08:08:13

Collection date (dd MMM yyyy)			8 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:15	8 OCT 2020 11:15
Nasopharyngeal Swab 2	No		

US3542168

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Oct 2020 04:17:01

Generated On: 10 Jun 2021 08:08:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542168

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Oct 2020 18:46:00

Generated On: 10 Jun 2021 08:08:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542168

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Oct 2020 18:46:00

Generated On: 10 Jun 2021 08:08:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542168

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 30 Oct 2020 01:28:16

Generated On: 10 Jun 2021 08:08:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542168

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 30 Oct 2020 01:28:16

Generated On: 10 Jun 2021 08:08:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542168

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 31 Oct 2020 18:33:49

Generated On: 10 Jun 2021 08:08:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542168

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 31 Oct 2020 18:33:49

Generated On: 10 Jun 2021 08:08:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542168

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 20 Nov 2020 04:15:40

Generated On: 10 Jun 2021 08:08:13

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	VISIT3

US3542168

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Nov 2020 04:15:40

Generated On: 10 Jun 2021 08:08:13

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)	12:56 (24 HR)
Vital Signs Date and Time (derived)	12 NOV 2020 12:56
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3542168

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Nov 2020 04:15:40

Generated On: 10 Jun 2021 08:08:13

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.

US3542168

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Nov 2020 04:15:40

Generated On: 10 Jun 2021 08:08:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 NOV 2020
Collection time (00:00-23:59)	12:57 (24 HR)
Collection date and time (derived)	12 NOV 2020 12:57

US3542168

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 20 Nov 2020 04:15:40

Generated On: 10 Jun 2021 08:08:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 DEC 2020 09:10:40

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3542168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT	DAY 99
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	09 DEC 2020 10:08:14
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3542168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 DEC 2020 09:33:42

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3542168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

DAY 113

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 09:43:24

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2020 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2020 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

Date and time of submission	
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

07 JAN 2021 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

DAY 138

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

21 JAN 2021 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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 <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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

28 JAN 2021 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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 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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

04 FEB 2021 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

DAY 159

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

18 FEB 2021 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

DAY 173

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

25 FEB 2021 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

11 MAR 2021 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

18 MAR 2021 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

21 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2021 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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 <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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

28 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2021 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

DAY 229

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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 ☐

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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 ☐

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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 ☐

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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 ☐

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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 ☐

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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="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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	15 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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 ☐

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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 ☐

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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 ☐

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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
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Patient Cloud Close Date & Time	09 DEC 2021 23:59
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US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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 ☐

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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 ☐

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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 ☐

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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 ☐

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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 ☐

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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 ☐

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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 ☐

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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 ☐

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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 ☐

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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 ☐

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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 ☐

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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 ☐

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

DAY 621

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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 ☐

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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 ☐

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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 ☐

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2022 00:01
Patient Cloud Close Date & Time	28 JUL 2022 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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 ☐

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 SEP 2022 00:01
Patient Cloud Close Date & Time	08 SEP 2022 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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 ☐

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	09 OCT 2022 00:01
Patient Cloud Close Date & Time	13 OCT 2022 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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 ☐

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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 ☐

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	23 OCT 2022 00:01
Patient Cloud Close Date & Time	27 OCT 2022 23:59

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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 ☐

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3542168

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Dec 2020 16:08:36

Generated On: 10 Jun 2021 08:08:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542168

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Dec 2020 16:08:36

Generated On: 10 Jun 2021 08:08:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542168

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 13 Jan 2021 03:45:28

Generated On: 10 Jun 2021 08:08:13

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

US3542168

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 13 Jan 2021 03:45:28

Generated On: 10 Jun 2021 08:08:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542168

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 17:03:54

Generated On: 10 Jun 2021 08:08:13

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3542168

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 17:03:54

Generated On: 10 Jun 2021 08:08:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542168

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 01:13:07

Generated On: 10 Jun 2021 08:08:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542168

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 01:13:07

Generated On: 10 Jun 2021 08:08:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542168

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 21:43:12

Generated On: 10 Jun 2021 08:08:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3542168

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 21:43:12

Generated On: 10 Jun 2021 08:08:13

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) _____

US3542168

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 21:43:12

Generated On: 10 Jun 2021 08:08:13

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.

US3542168

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 21:43:12

Generated On: 10 Jun 2021 08:08:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	01 APR 2021
Collection time (00:00-23:59)	10:35 (24 HR)
Collection date and time (derived)	01 APR 2021 10:35

US3542168

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:43:12

Generated On: 10 Jun 2021 08:08:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542168

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542168

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3542168

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:08:13

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"/>

US3542168

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:08:13

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3542168

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

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 17:03:54

Generated On: 10 Jun 2021 08:08:13

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

Visit date (dd MMM yyyy)	05 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3542168

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

Form: Unblinding

Data signed: (b) (4) 12 Mar 2021 22:45:16

Generated On: 10 Jun 2021 08:08:13

Date of updated informed consent (<i>dd MMM yyyy</i>)	05 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>)	05 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3542168

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Feb 2021 17:03:54

Generated On: 10 Jun 2021 08:08:13

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

US3542168

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 17:03:54

Generated On: 10 Jun 2021 08:08:13

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)	05 FEB 2021
Time of assessment (00:00-23:59)	12:34 (24 HR)
Vital Signs Date and Time (derived)	05 FEB 2021 12:34
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	95 mmHg
Diastolic Blood Pressure units	MMHG

US3542168

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 17:03:54

Generated On: 10 Jun 2021 08:08:13

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)	05 FEB 2021
Time of assessment (00:00-23:59)	13:37 (24 HR)
Vital Signs Date and Time (derived)	05 FEB 2021 13:37
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)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	161 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

US3542168

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

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 17:03:54

Generated On: 10 Jun 2021 08:08:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 FEB 2021

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

US3542168

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

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 17:03:54

Generated On: 10 Jun 2021 08:08:13

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) 05 FEB 2021

What was the treatment time? (00:00-23:59) 13:05 (24 HR)

Treatment Date and Time (derived) 05 FEB 2021 13:05

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

US3542168

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 17:03:54

Generated On: 10 Jun 2021 08:08:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	05 FEB 2021
Collection time (00:00-23:59)	12:29 (24 HR)
Collection date and time (derived)	05 FEB 2021 12:29

US3542168

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Feb 2021 17:03:54

Generated On: 10 Jun 2021 08:08:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	05 FEB 2021
Collection time (00:00 - 23:59)	12:33
Collection Date and Time (derived)	05 FEB 2021 12:33

US3542168

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

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 17:03:54

Generated On: 10 Jun 2021 08:08:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542168

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 04:03:53

Generated On: 10 Jun 2021 08:08:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542168

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:03:53

Generated On: 10 Jun 2021 08:08:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

OLD29 Placebo Flag

1

US3542168

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 10 Mar 2021 01:13:07

Generated On: 10 Jun 2021 08:08:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3542168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 10 Mar 2021 01:13:07

Generated On: 10 Jun 2021 08:08:13

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)	08 MAR 2021
Time of assessment (00:00-23:59)	12:34 (24 HR)
Vital Signs Date and Time (derived)	08 MAR 2021 12:34
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	166 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	97 mmHg
Diastolic Blood Pressure units	MMHG

US3542168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 10 Mar 2021 01:13:07

Generated On: 10 Jun 2021 08:08:13

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
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="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
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	

US3542168

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 10 Mar 2021 01:13:07

Generated On: 10 Jun 2021 08:08:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 MAR 2021

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

US3542168

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 10 Mar 2021 01:13:07

Generated On: 10 Jun 2021 08:08:13

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) 08 MAR 2021

What was the treatment time? (00:00-23:59) 12:50 (24 HR)

Treatment Date and Time (derived) 08 MAR 2021 12:50

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

US3542168

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 01:13:07

Generated On: 10 Jun 2021 08:08:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542168

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 20:18:34

Generated On: 10 Jun 2021 08:08:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542168

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 20:18:34

Generated On: 10 Jun 2021 08:08:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542168

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 18:27:39

Generated On: 10 Jun 2021 08:08:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3542168

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 21:43:12

Generated On: 10 Jun 2021 08:08:13

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) _____

US3542168

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 21:43:12

Generated On: 10 Jun 2021 08:08:13

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.

US3542168

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 21:43:12

Generated On: 10 Jun 2021 08:08:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	01 APR 2021
Collection time (00:00-23:59)	10:35 (24 HR)
Collection date and time (derived)	01 APR 2021 10:35

US3542168

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 18 Sep 2020 17:11:07

Generated On: 10 Jun 2021 08:08:13

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 04 Feb 2021 22:37:18

Generated On: 10 Jun 2021 08:08:13

AEID	USA-US084-2020-MRNA-1273-P30 1000001
Adverse event	ANXIETY EXACERBATION
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)	10 SEP 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)	18 SEP 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 type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	10 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	18 SEP 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) 04 Feb 2021 22:37:18

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 04 Feb 2021 22:37:18

Generated On: 10 Jun 2021 08:08:13

PARTICIPANT REPORTED TO SITE ON 18SEP2020 THAT HE HAD JUST BEEN DISCHARGED FROM HOSPITAL THIS DAY AFTER HAVING BEEN ADMITTED TO THE PSYCHIATRIC SERVICE ON 10SEP2020 DUE TO WORSENERD ANXIETY. HE STATES THAT HE HAS PRE-EXISTING DIAGNOSES OF ANXIETY AND DEPRESSION FOR THE PAST 20 YEARS THAT WERE NOT RELATED TO THE STUDY TEAM AT SCREENING/ENROLLMENT. HE HAS BEEN TREATED FOR THE PAST YEAR WITH REMERON 15MG/DAY (ALSO NOT REPORTED TO THE STUDY TEAM AT SCREENING/ENROLLMENT).

ACCORDING TO THE PARTICIPANT, HIS GIRLFRIEND WAS RECENTLY DIAGNOSED WITH CERVICAL CANCER, WHICH LED TO WORSENERD SYMPTOMS OF ANXIETY ON 10SEP2020, PROMPTING HIM TO GO TO THE EMERGENCY DEPARTMENT OF A LOCAL COMMUNITY HOSPITAL (NOT AT THE STUDY SITE). HE WAS ADMITTED TO THE PSYCHIATRY SERVICE FOR

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Folder: Adverse Events

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MEDICATION ADJUSTMENT.
HIS DOSE OF REMERON WAS
INCREASED TO 30MG/DAY
ACCORDING TO THE
PARTICIPANT. DURING HIS
IN-PATIENT STAY HIS
SYMPTOMS OF ANXIETY
IMPROVED AND HE WAS
THEREFORE DISCHARGED
HOME THE MORNING OF
18SEP2020. HE WILL
FOLLOW-UP WITH HIS
REGULAR PSYCHIATRIST.

HE DENIES HAVING ANY
POTENTIAL COVID-19
SYMPTOMS: NO FEVER,
CHILLS, DYSPNEA, COUGH,
LOSS OF TASTE OR SMELL,
RHINORRHEA, NASAL
CONGESTION, SORE THROAT,
MYALGIAS, ARTHRALGIAS,
HEADACHE, FATIGUE, NAUSEA,
OR DIARRHEA. NO RECENT
TRAVEL OR SICK CONTACTS.

HE RECEIVED HIS FIRST DOSE
OF VACCINE/PLACEBO ON
04SEPT2020.

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 04 Feb 2021 22:37:18

Generated On: 10 Jun 2021 08:08:13

AEID	USA-US084-2020-MRNA-1273-P30 1000001
Adverse event	ANXIETY EXACERBATION
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)	19 SEP 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)	23 SEP 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)	19 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	23 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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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	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 04 Feb 2021 22:37:18

Generated On: 10 Jun 2021 08:08:13

PARTICIPANT CALLED STUDY
TEAM ON 24SEP2020 TO
REPORT THAT HE HAD BEEN
RE-ADMITTED TO THE
PSYCHIATRIC WARD OF A
LOCAL HOSPITAL ON 19SEP2020
DUE TO RECURRENCE OF
SYMPTOMS OF SEVERE
ANXIETY. WHILE IN HOSPITAL
HE WAS DIAGNOSED WITH
BORDERLINE PERSONALITY
DISORDER AND STARTED ON
BOTH LITHIUM AND
MIRTAZIPINE, WITH
IMPROVEMENT OF SYMPTOMS.
HE WAS DISCHARGED ON
23SEP2020 WITH FOLLOW-UP
PLANNED WITH OUTPATIENT
PSYCHIATRY.

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 04 Feb 2021 22:37:18

Generated On: 10 Jun 2021 08:08:13

AEID	USA-US084-2020-MRNA-1273-P30 1000001
Adverse event	DEPRESSION EXACERBATION
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)	19 SEP 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)	23 SEP 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)	19 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	23 SEP 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 (3)

Data signed: (b) (4) 04 Feb 2021 22:37:18

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 04 Feb 2021 22:37:18

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PARTICIPANT WENT TO
EMERGENCY DEPARTMENT TO
BE TREATED FOR LOWER LEG
PAIN, THOUGHT TO BE
ATTRIBUTED TO SICKLE CELL
DISEASE. HE WAS THEN
ADMITTED TO THE PSYCH
DEPARTMENT FOR
EXACERBATION OF CHRONIC
ANXIETY AND DEPRESSION. HE
WAS DIAGNOSED WITH PTSD
AND BORDERLINE
PERSONALITY DISORDER AND
GIVEN MEDICATION FOR
TREATMENT.

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 04 Feb 2021 22:37:18

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AEID

Adverse event

LOWER LEG PAIN

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)

18 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 04 Feb 2021 22:37:18

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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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input 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 _____	
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 (5)

Data signed: (b) (4) 04 Feb 2021 22:37:18

Generated On: 10 Jun 2021 08:08:13

AEID

Adverse event

RHINORRHEA

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 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

23 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 04 Feb 2021 22:37:18

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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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input 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: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 04 Feb 2021 22:37:18

Generated On: 10 Jun 2021 08:08:13

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	21 OCT 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)	23 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input 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 (6)

Data signed: (b) (4) 04 Feb 2021 22:37:18

Generated On: 10 Jun 2021 08:08:13

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input 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 _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 04 Feb 2021 22:37:18

Generated On: 10 Jun 2021 08:08:13

AEID

Adverse event

RIGHT TRAPEZIUS STRAIN

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)

10 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

22 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 04 Feb 2021 22:37:18

Generated On: 10 Jun 2021 08:08:13

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 24 Sep 2020 11:50:06

Generated On: 10 Jun 2021 08:08:13

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 24 Mar 2021 16:47:23

Generated On: 10 Jun 2021 08:08:13

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 24 Mar 2021 16:47:23

Generated On: 10 Jun 2021 08:08:13

	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 (2)

Data signed: (b) (4) 24 Mar 2021 16:47:23

Generated On: 10 Jun 2021 08:08:13

Name of Medication REMERON

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED ANXIETY
DISORDER

Dose per administration 15

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 (2)

Data signed: (b) (4) 24 Mar 2021 16:47:23

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	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)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	10 SEP 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) 24 Mar 2021 16:47:23

Generated On: 10 Jun 2021 08:08:13

Name of Medication REMERON

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED ANXIETY
DISORDER EXACERBATION

Dose per administration 30

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 (3)

Data signed: (b) (4) 24 Mar 2021 16:47:23

Generated On: 10 Jun 2021 08:08:13

	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)		10 SEP 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 (4)

Data signed: (b) (4) 24 Mar 2021 16:47:23

Generated On: 10 Jun 2021 08:08:13

Name of Medication MIRTAZAPINE

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION EXACERBATION

Dose per administration 30

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) 24 Mar 2021 16:47:23

Generated On: 10 Jun 2021 08:08:13

	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)		20 SEP 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 (5)

Data signed: (b) (4) 24 Mar 2021 16:47:23

Generated On: 10 Jun 2021 08:08:13

Name of Medication LITHIUM

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION AND ANXIETY
EXACERBATION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 24 Mar 2021 16:47:23

Generated On: 10 Jun 2021 08:08:13

	Intraocular	<input type="radio"/>
	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)		20 SEP 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 (6)

Data signed: (b) (4) 24 Mar 2021 16:47:23

Generated On: 10 Jun 2021 08:08:13

Name of Medication PRAZOSIN

Prophylaxis Yes ☐
No ☒

Indication PTSD

Dose per administration 3

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) 24 Mar 2021 16:47:23

Generated On: 10 Jun 2021 08:08:13

	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)		20 SEP 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 (7)

Data signed: (b) (4) 24 Mar 2021 16:47:23

Generated On: 10 Jun 2021 08:08:13

Name of Medication HYDROXYUREA

Prophylaxis Yes ☐
No ☒

Indication SICKLE CELL DISEASE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 24 Mar 2021 16:47:23

Generated On: 10 Jun 2021 08:08:13

	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 MAY 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 (8)

Data signed: (b) (4) 24 Mar 2021 16:47:23

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Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication LOWER LEG PAIN

Dose per administration 4

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) 24 Mar 2021 16:47:23

Generated On: 10 Jun 2021 08:08:13

	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)		19 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 24 Mar 2021 16:47:23

Generated On: 10 Jun 2021 08:08:13

Name of Medication DILAUDID

Prophylaxis Yes ☐
No ☒

Indication LOWER LEG PAIN

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

TWICE

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 24 Mar 2021 16:47:23

Generated On: 10 Jun 2021 08:08:13

	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)		19 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 24 Mar 2021 16:47:23

Generated On: 10 Jun 2021 08:08:13

Name of Medication BENADRYL

Prophylaxis Yes ☐
No ☒

Indication LOWER LEG PAIN

Dose per administration 25

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 (10)

Data signed: (b) (4) 24 Mar 2021 16:47:23

Generated On: 10 Jun 2021 08:08:13

	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)		19 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 24 Mar 2021 16:47:23

Generated On: 10 Jun 2021 08:08:13

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication SICKLE CELL DISEASE

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 24 Mar 2021 16:47:23

Generated On: 10 Jun 2021 08:08:13

	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 AUG 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 (12)

Data signed: (b) (4) 24 Mar 2021 16:47:23

Generated On: 10 Jun 2021 08:08:13

Name of Medication MOTRIN

Prophylaxis Yes ☐
No ☒

Indication RIGHT TRAPEZIUS STRAIN.

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

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 24 Mar 2021 16:47:23

Generated On: 10 Jun 2021 08:08:13

	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)		10 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)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 24 Mar 2021 16:47:23

Generated On: 10 Jun 2021 08:08:13

Name of Medication BC POWDER (ASPIRIN)

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 1

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

If dose unit is Other, specify PACKET

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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US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 24 Mar 2021 16:47:23

Generated On: 10 Jun 2021 08:08:13

	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)	23 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	25 OCT 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"/>

US3542168

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 04 Feb 2021 22:37:18

Generated On: 10 Jun 2021 08:08:13

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3542168

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 21 Oct 2020 18:46:00

Generated On: 10 Jun 2021 08:08:13

Date of dosing discontinuation (dd MMM yyyy)	08 OCT 2020
--	-------------

Primary reason for dosing discontinuation	AE (specify) <input type="checkbox"/>
	SAE (specify) <input type="checkbox"/>
	Death <input type="checkbox"/>
	Lost To Follow-up <input type="checkbox"/>
	Physician decision (specify) <input checked="" 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	PHYSICIAN WITHHELD DOSE DUE TO HOSPITAL ADMISSIONS FOR PSYCHIATRIC REASONS
---	--

US3542168

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:08:13

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 ☐

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 01 Dec 2020 16:57:53

Generated On: 10 Jun 2021 08:08:13

SAEID	USA-US084-2020-MRNA-1273-P301000001
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	DC
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 01 Dec 2020 16:57:53

Generated On: 10 Jun 2021 08:08:13

SAEID	USA-US084-2020-MRNA-1273-P301000001
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	DC
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	20/SEP/2020 13:53
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

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 01 Dec 2020 16:57:53

Generated On: 10 Jun 2021 08:08:13

SAEID	USA-US084-2020-MRNA-1273-P301000001
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	DC
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	28/SEP/2020 10:01
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

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 01 Dec 2020 16:57:53

Generated On: 10 Jun 2021 08:08:13

SAEID	USA-US084-2020-MRNA-1273-P301000001
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	DC
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	30/SEP/2020 17:33
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

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 01 Dec 2020 16:57:53

Generated On: 10 Jun 2021 08:08:13

SAEID	USA-US084-2020-MRNA-1273-P301000001
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	DC
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	28/OCT/2020 14:06
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

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 01 Dec 2020 16:57:53

Generated On: 10 Jun 2021 08:08:13

SAEID	USA-US084-2020-MRNA-1273-P301000001
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	DC
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	23/NOV/2020 09:38
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

US3542168 (Prod: George Washington University)

US3542168

Form: Participant Creation

Generated On: 10 Jun 2021 08:08:13

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:59:43
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:50:51
User entered 'US3542168'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:34:43

US3542168

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:08:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:50:51
User entered 'Yes (Y)'	(b) (4) Elissa Malkin (b) (4)	04 Sep 2020 19:49:00

US3542168

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:50:51
User entered '04 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:34:44

US3542168

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:50:51
User entered 'Clinic (Clinic)'	(b) (4) Elissa Malkin (b) (4)	04 Sep 2020 19:49:00

US3542168

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:08:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered 'SCRN'	System	04 Sep 2020 19:49:00

US3542168

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:13

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User closed query 'Per CDM: Kindly complete all the forms for this Visit.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 06:34:44
Query 'Per CDM: Kindly complete all the forms for this Visit.' answered with 'Forms completed' (Site from DM).	Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 18:02:45
User opened query 'Per CDM: Kindly complete all the forms for this Visit.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 11:47:10
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:50:51
User entered (b) (6) 1966'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:34:46

US3542168

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:13

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '54'	(b) (4) Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 18:01:49

US3542168

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:13

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered 'YEARS'	System	22 Sep 2020 18:01:49

US3542168

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:13

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered '54'	System	04 Sep 2020 19:49:41

US3542168

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:13

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'Male (M)'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 18:01:49

US3542168

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:13

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 18:01:49

US3542168

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:13

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 18:01:49

US3542168

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:13

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'l'	(b) (4) Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 18:01:49

US3542168

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:13

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 18:01:49

US3542168

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:13

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '0'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 18:01:49

US3542168

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:13

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 18:01:49

US3542168

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:13

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 18:01:49

US3542168

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:13

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered empty.	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 18:01:49
	(b) (4)	

US3542168

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:13

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 18:01:49

US3542168

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:13

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '0'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 18:01:49
	(b) (4)	

US3542168

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:50:51
User entered '4 Sep 2020'	(b) (4) Elissa Malkin (b) (4)	04 Sep 2020 19:49:41

US3542168

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered 'Sep 2020'	System	04 Sep 2020 19:49:41

US3542168

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered '2020'	System	04 Sep 2020 19:49:41

US3542168

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:13

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:50:51
User entered 'Amendment 3 (3)'	(b) (4) Elissa Malkin (b) (4)	04 Sep 2020 19:49:41

US3542168

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:50:51
User entered 'Yes (Y)'	(b) (4) Elissa Malkin (b) (4)	04 Sep 2020 19:49:41

US3542168

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:50:51
User entered empty.	(b) (4) Elissa Malkin (b) (4)	04 Sep 2020 19:49:41

US3542168

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:13

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:50:51
User entered empty.	(b) (4) Elissa Malkin (b) (4)	04 Sep 2020 19:49:41

US3542168

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:13

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:50:51
User entered 'No (N)'	(b) (4) Elissa Malkin (b) (4)	04 Sep 2020 19:49:41

US3542168

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:13

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:50:51
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:34:44

US3542168

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:13

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered 'I'	System	04 Sep 2020 19:49:54

US3542168

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:50:51
User entered 'Yes (Y)'	(b) (4) Elissa Malkin (b) (4)	04 Sep 2020 19:49:54

US3542168

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:08:13

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Sep 2020 18:50:31

US3542168

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
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)	21 Sep 2020 18:52:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 18:52:54
Data point term sent to Coder	System	21 Sep 2020 18:51:41
User entered 'hypertension'	Taylor Ladson (b) (4)	21 Sep 2020 18:50:45

US3542168

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'un UNK 2018'	(b) (4) Taylor Ladson (b) (4)	21 Sep 2020 18:50:45

US3542168

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Sep 2020 18:50:45

US3542168

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Sep 2020 18:50:45

US3542168

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Sep 2020 18:50:45

US3542168

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Sep 2020 18:50:45

US3542168

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered 'Jan 2018'	System	21 Sep 2020 18:50:45

US3542168

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered '2018'	System	21 Sep 2020 18:50:45

US3542168

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered empty.	System	21 Sep 2020 18:50:45

US3542168

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered empty.	System	21 Sep 2020 18:50:45

US3542168

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin grafts, PT: Skin graft, LLT: Skin graft - version MedDRA\\23.0.	Coder Import (b) (4)	10 Oct 2020 06:31:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Oct 2020 06:31:19
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Data point term sent to Coder	System (b) (4)	21 Sep 2020 18:51:41
User entered 'skin grafts for burn'	Taylor Ladson (b) (4)	21 Sep 2020 18:50:59

US3542168

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'un UNK 1992'	(b) (4) Taylor Ladson (b) (4)	21 Sep 2020 18:50:59

US3542168

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Sep 2020 18:50:59

US3542168

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Sep 2020 18:50:59

US3542168

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'un UNK 1992'	(b) (4) Taylor Ladson (b) (4)	21 Sep 2020 18:50:59

US3542168

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Sep 2020 18:50:59

US3542168

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered 'Jan 1992'	System	21 Sep 2020 18:50:59

US3542168

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered '1992'	System	21 Sep 2020 18:50:59

US3542168

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered 'Jan 1992'	System	21 Sep 2020 18:50:59

US3542168

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered '1992'	System	21 Sep 2020 18:50:59

US3542168

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety disorders NEC, PT: Generalised anxiety disorder, LLT: Generalized anxiety disorder - version MedDRA\23.0.	Coder Import (b) (4)	21 Sep 2020 18:52:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Sep 2020 18:52:55
Data point term sent to Coder	System	21 Sep 2020 18:51:39
User entered 'generalized anxiety disorder'	Taylor Ladson (b) (4)	21 Sep 2020 18:51:06

US3542168

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'un UNK 2000'	(b) (4) Taylor Ladson (b) (4)	21 Sep 2020 18:51:06

US3542168

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Sep 2020 18:51:06

US3542168

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Sep 2020 18:51:06

US3542168

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Sep 2020 18:51:06

US3542168

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Sep 2020 18:51:06

US3542168

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered 'Jan 2000'	System	21 Sep 2020 18:51:06

US3542168

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:13

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered '2000'	System	21 Sep 2020 18:51:06

US3542168

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered empty.	System	21 Sep 2020 18:51:06

US3542168

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered empty.	System	21 Sep 2020 18:51:06

US3542168

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 18:52:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 18:52:54
Data point term sent to Coder	System	21 Sep 2020 18:51:41
User entered 'depression'	Taylor Ladson (b) (4)	21 Sep 2020 18:51:14

US3542168

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'un UNK 2000'	(b) (4) Taylor Ladson (b) (4)	21 Sep 2020 18:51:14

US3542168

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Sep 2020 18:51:14

US3542168

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Sep 2020 18:51:14

US3542168

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Sep 2020 18:51:14

US3542168

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Sep 2020 18:51:14

US3542168

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered 'Jan 2000'	System	21 Sep 2020 18:51:14

US3542168

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered '2000'	System	21 Sep 2020 18:51:14

US3542168

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered empty.	System	21 Sep 2020 18:51:14

US3542168

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered empty.	System	21 Sep 2020 18:51:14

US3542168

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Stress disorders, PT: Post-traumatic stress disorder, LLT: Post-traumatic stress disorder - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:44:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:44:50
Data point term sent to Coder	System	30 Sep 2020 14:43:35
User entered 'PTSD'	Taylor Ladson (b) (4)	30 Sep 2020 14:42:49

US3542168

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'UN UNK 2000'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:42:49

US3542168

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '0'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:42:49

US3542168

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:42:49

US3542168

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:42:49
	(b) (4)	

US3542168

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '0'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:42:49

US3542168

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered 'Jan 2000'	System	30 Sep 2020 14:42:49

US3542168

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered '2000'	System	30 Sep 2020 14:42:49

US3542168

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered empty.	System	30 Sep 2020 14:42:49

US3542168

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered empty.	System	30 Sep 2020 14:42:49

US3542168

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User coded data point as SOC: Psychiatric disorders, HLT: Personality disorders and disturbances in behaviour, HLT: Personality disorders with dramatic behaviour (Cluster B), PT: Borderline personality disorder, LLT: Borderline personality disorder - version MedDRA\23.0.	Coder Import (b) (4)	30 Sep 2020 14:44:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Sep 2020 14:44:50
Data point term sent to Coder	System	30 Sep 2020 14:43:37
User entered 'Borderline personality disorder'	Taylor Ladson (b) (4)	30 Sep 2020 14:43:02

US3542168

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'un UNK 2000'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:43:02

US3542168

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '0'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:43:02

US3542168

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:43:02

US3542168

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:43:02

US3542168

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '0'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:43:02

US3542168

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered 'Jan 2000'	System	30 Sep 2020 14:43:02

US3542168

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:13

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered '2000'	System	30 Sep 2020 14:43:02

US3542168

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered empty.	System	30 Sep 2020 14:43:02

US3542168

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered empty.	System	30 Sep 2020 14:43:02

US3542168

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Blood and lymphatic system disorders congenital, HLT: Haemoglobinopathies congenital, PT: Sick cell disease, LLT: Sick cell disease - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:44:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:44:50
Data point term sent to Coder	System	30 Sep 2020 14:43:38
User entered 'sickle cell disease'	Taylor Ladson (b) (4)	30 Sep 2020 14:43:13

US3542168

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User closed query 'Start date is prior to Date of Birth. System Please correct.' (Site from System).	(b) (4)	30 Sep 2020 14:44:14
User entered 'UN (b) (6) 1966' reason for change: Data Entry Error	Taylor Ladson (b) (4)	30 Sep 2020 14:44:14
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	(b) (4)	30 Sep 2020 14:43:13
User entered 'un UNK 1966'	System	30 Sep 2020 14:43:13
	Taylor Ladson (b) (4)	30 Sep 2020 14:43:13
	(b) (4)	

US3542168

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '0'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:43:13

US3542168

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:43:13

US3542168

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:43:13
	(b) (4)	

US3542168

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '0'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:43:13

US3542168

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered (b) (6) 1966'	System	30 Sep 2020 14:44:14
User entered (b) (6) 1966'	System	30 Sep 2020 14:43:13

US3542168

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:13

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered '1966'	System	30 Sep 2020 14:43:13

US3542168

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered empty.	System	30 Sep 2020 14:43:13

US3542168

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered empty.	System	30 Sep 2020 14:43:13

US3542168

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:08:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety disorders NEC, PT: Anxiety disorder, LLT: Anxiety disorder - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:44:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:44:50
Data point term sent to Coder	System	30 Sep 2020 14:43:38
User entered 'anxiety disorder'	Taylor Ladson (b) (4)	30 Sep 2020 14:43:26

US3542168

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'un UNK 2000'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:43:26

US3542168

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:08:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '0'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:43:26

US3542168

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:08:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:43:26

US3542168

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:43:26

US3542168

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:08:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '0'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:43:26

US3542168

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered 'Jan 2000'	System	30 Sep 2020 14:43:26

US3542168

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:08:13

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered '2000'	System	30 Sep 2020 14:43:26

US3542168

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered empty.	System	30 Sep 2020 14:43:26

US3542168

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered empty.	System	30 Sep 2020 14:43:26

US3542168

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:20:42

US3542168

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '04 Sep 2020'	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:20:42

US3542168

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '15:38'	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:20:42

US3542168

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered '04 Sep 2020 15:38'	System	22 Sep 2020 15:20:42

US3542168

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '68' in	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:20:42
DataPoint set to visible.	(b) (4) System	04 Sep 2020 19:49:54

US3542168

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '145' lb	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:20:42
DataPoint set to visible.	(b) (4) System	04 Sep 2020 19:49:54

US3542168

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered '22.09327'	System	22 Sep 2020 15:20:42
DataPoint set to visible.	System	04 Sep 2020 19:49:54

US3542168

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered 'kg/m2'	System	22 Sep 2020 15:20:42
DataPoint set to visible.	System	04 Sep 2020 19:49:54

US3542168

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:20:42

US3542168

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered empty.	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:20:42

US3542168

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered empty.	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:20:42
	(b) (4)	

US3542168

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:20:42

US3542168

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered 'bpm'	System	22 Sep 2020 15:20:42

US3542168

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:20:42

US3542168

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered 'breaths/min'	System	22 Sep 2020 15:20:42

US3542168

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:20:42

US3542168

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered 'mmHg'	System	22 Sep 2020 15:20:42

US3542168

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:20:42

US3542168

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User entered 'mmHg'	System	22 Sep 2020 15:20:42

US3542168

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47

US3542168

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47

US3542168

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:45:28
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	11 Jan 2021 21:17:28
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	Erika Faust (b) (4)	11 Jan 2021 21:17:28
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
	(b) (4)	
User entered 'No (N)'	Taylor Ladson (b) (4)	22 Sep 2020 15:20:21
	(b) (4)	

US3542168

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:45:28
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	11 Jan 2021 21:17:28
	(b) (4)	
User entered '04 Sep 2020' reason for change: New Information	Erika Faust (b) (4)	11 Jan 2021 21:17:28
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
	(b) (4)	
User entered empty.	Taylor Ladson (b) (4)	22 Sep 2020 15:20:21
	(b) (4)	

US3542168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:23:04

US3542168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:23:04

US3542168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:13

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)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:23:04

US3542168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:13

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)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:23:04

US3542168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:23:04

US3542168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:13

[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)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:23:04

US3542168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:13

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)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:23:04

US3542168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:13

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)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:23:04

US3542168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:13

[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)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:23:04

US3542168

Folder: Screening

Form: Risk of Exposure

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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)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:23:04

US3542168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:13

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)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:23:04

US3542168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:13

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:23:04

US3542168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:13

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered empty.	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:23:04

US3542168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:13

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '0'	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:23:04

US3542168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '0'	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:23:04

US3542168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:13

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)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '0'	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:23:04

US3542168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:13

[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)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '0'	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:23:04

US3542168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:13

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)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '0'	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:23:04

US3542168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'l'	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:23:04

US3542168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:13

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '0'	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:23:04

US3542168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:13

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered empty.	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:23:04

US3542168

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:08:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:50:51
User entered 'Yes (Y)'	(b) (4) Elissa Malkin (b) (4)	04 Sep 2020 20:20:10

US3542168

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:50:51
User entered '4 Sep 2020'	Elissa Malkin (b) (4)	04 Sep 2020 20:20:10

US3542168

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:08:13

[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 07:43:23
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:50:51
User entered 'Clinic (Clinic)'	Elissa Malkin (b) (4)	04 Sep 2020 20:20:10

US3542168

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:08:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered 'VISIT1'	System	04 Sep 2020 20:20:10

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4)	05 Sep 2020 21:50:51
User entered '04 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:49:35

US3542168

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4)	05 Sep 2020 21:50:51
User entered '111966'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:49:35

US3542168

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:50:51
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:49:35

US3542168

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:13

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 07:43:23
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:19:58

US3542168

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:13

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 07:43:23
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:19:58

US3542168

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:19:58

US3542168

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:13

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:19:58

US3542168

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:13

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:19:58

US3542168

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	(b) (4)	
	Taylor Ladson (b) (4)	22 Sep 2020 15:19:58
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:29:34
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:29:32

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:21:21

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:21:21

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:21:21

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:21:21

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User accepted default value 'Pre-Dose (PREDOSE)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:21:21

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:21:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '04 Sep 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:21:21

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '15:38'	(b) (4) Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:21:21

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered '04 Sep 2020 15:38'	System	22 Sep 2020 15:21:21

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '98.8' F	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:21:21

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'Oral (Oral)'	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:21:21

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered empty.	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:21:21

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '56'	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:21:21

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered 'bpm'	System	22 Sep 2020 15:21:21

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '16'	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:21:21

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered 'breaths/min'	System	22 Sep 2020 15:21:21

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '154'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:21:21

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered 'mmHg'	System	22 Sep 2020 15:21:21

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '92'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:21:21

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered 'mmHg'	System	22 Sep 2020 15:21:21

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:21:21

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:21:21

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User accepted default value 'Post-Dose (POSTDOSE)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:58

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:23:58

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '04 Sep 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:58

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '16:48'	(b) (4) Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:58

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered '04 Sep 2020 16:48'	System	22 Sep 2020 15:23:58

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '98.8' F	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:58

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'Oral (Oral)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:58

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:58

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '60'	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:23:58

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered 'bpm'	System	22 Sep 2020 15:23:58

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '16'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:58

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered 'breaths/min'	System	22 Sep 2020 15:23:58

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '144'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:58

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered 'mmHg'	System	22 Sep 2020 15:23:58

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '94'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:58

US3542168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered 'mmHg'	System	22 Sep 2020 15:23:58

US3542168

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:45:28
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	11 Jan 2021 21:18:00
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Erika Faust (b) (4)	11 Jan 2021 21:18:00
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'Yes (Y)'	(b) (4)	
	Taylor Ladson (b) (4)	22 Sep 2020 15:20:15
	(b) (4)	

US3542168

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:45:28
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	11 Jan 2021 21:18:00
User entered empty; reason for change New Information	(b) (4)	
	Erika Faust (b) (4)	11 Jan 2021 21:18:00
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '04 Sep 2020'	(b) (4)	
	Taylor Ladson (b) (4)	22 Sep 2020 15:20:15
	(b) (4)	

US3542168

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:50:51
User entered 'Yes (Y)'	(b) (4) Elissa Malkin (b) (4)	04 Sep 2020 20:20:50

US3542168

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:50:51
User entered empty.	(b) (4) Elissa Malkin (b) (4)	04 Sep 2020 20:20:50

US3542168

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

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 07:43:23
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:50:51
User entered empty.	Elissa Malkin (b) (4)	04 Sep 2020 20:20:50

US3542168

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 20:20:50

US3542168

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:52
Signature has been broken.	(b) (4)	
	Hannah Yellin (b) (4)	18 Feb 2021 16:21:49
	(b) (4)	
User entered '04 Sep 2020' reason for change: Data Entry Error	Hannah Yellin (b) (4)	18 Feb 2021 16:21:49
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:50:51
	(b) (4)	
User entered '4 Sep 2020'	Elissa Malkin (b) (4)	04 Sep 2020 20:20:50
	(b) (4)	

US3542168

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:25:52
User entered '16:18' reason for change: Per Query Resolution	Hannah Yellin (b) (4)	18 Feb 2021 16:21:34
Signature has been broken.	Hannah Yellin (b) (4)	18 Feb 2021 16:20:49
User entered '16:19' reason for change: Per Query Resolution	Hannah Yellin (b) (4)	18 Feb 2021 16:20:49
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:50:51
User entered '16:18'	Elissa Malkin (b) (4)	04 Sep 2020 20:20:50

US3542168

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered '04 Sep 2020 16:18'	System	18 Feb 2021 16:21:49
User entered '4 Sep 2020 16:18'	System	18 Feb 2021 16:21:34
User entered '4 Sep 2020 16:19'	System	18 Feb 2021 16:20:49
User entered '4 Sep 2020 16:18'	System	04 Sep 2020 20:20:50

US3542168

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:50:51
User entered 'Left Arm (LEFT ARM)'	(b) (4) Elissa Malkin (b) (4) (b) (4)	04 Sep 2020 20:20:50

US3542168

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered 'ONCE'	System	04 Sep 2020 20:20:50

US3542168

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 20:20:50

US3542168

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:23:22

US3542168

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:13

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '04 Sep 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:22

US3542168

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:13

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '15:56'	(b) (4) Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:22

US3542168

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered '04 Sep 2020 15:56'	System	22 Sep 2020 15:23:22

US3542168

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:08:13

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '04 Sep 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:33

US3542168

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:08:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:33

US3542168

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:08:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:33

US3542168

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:08:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '15:58'	(b) (4) Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:33

US3542168

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered '04 Sep 2020 15:58'	System	22 Sep 2020 15:23:33

US3542168

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:08:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:33

US3542168

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:08:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	22 Sep 2020 15:23:33

US3542168

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:08:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:33

US3542168

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered empty.	System	22 Sep 2020 15:23:33

US3542168

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:28:58
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	16 Sep 2020 18:41:38

US3542168

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered 'l'	System	16 Sep 2020 18:41:38

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T16:52:01', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '9b59e169-ca1d-493c-935e-d14a027d5f70'	System	04 Sep 2020 20:52:33
User entered 'Yes (Y)'	System	04 Sep 2020 20:52:33

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T16:52:12', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '9b59e169-ca1d-493c-935e-d14a027d5f70'	System	04 Sep 2020 20:52:33
User entered '98.8'	System	04 Sep 2020 20:52:33

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T16:52:20', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '9b59e169-ca1d-493c-935e-d14a027d5f70'	System	04 Sep 2020 20:52:33
User entered 'No (N)'	System	04 Sep 2020 20:52:33

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T16:52:29', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '9b59e169-ca1d-493c-935e-d14a027d5f70'	System	04 Sep 2020 20:52:33
User entered '04 Sep 2020 16:52'	System	04 Sep 2020 20:52:33

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '04 Sep 2020 16:38'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '04 Sep 2020 19:08'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T20:12:14', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '4e571d18-005a-4f9d-8ee4-43d816fcb424'	System	05 Sep 2020 00:12:35
User entered 'Yes (Y)'	System	05 Sep 2020 00:12:35

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T20:12:21', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '4e571d18-005a-4f9d-8ee4-43d816fcb424'	System	05 Sep 2020 00:12:35
User entered '98.3'	System	05 Sep 2020 00:12:35

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T20:12:25', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '4e571d18-005a-4f9d-8ee4-43d816fcb424'	System	05 Sep 2020 00:12:35
User entered 'No (N)'	System	05 Sep 2020 00:12:35

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T20:12:32', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '4e571d18-005a-4f9d-8ee4-43d816fcb424'	System	05 Sep 2020 00:12:35
User entered '04 Sep 2020 20:12'	System	05 Sep 2020 00:12:35

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '04 Sep 2020 20:03'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 2'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-05T13:02:49', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '78427212-8449-4879-906d-f8070abc8f03'	System	05 Sep 2020 17:03:15
User entered 'Yes (Y)'	System	05 Sep 2020 17:03:15

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-05T13:03:02', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '78427212-8449-4879-906d-f8070abc8f03' User entered '98.3'	System	05 Sep 2020 17:03:15
	System	05 Sep 2020 17:03:15

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-05T13:03:06', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '78427212-8449-4879-906d-f8070abc8f03'	System	05 Sep 2020 17:03:15
User entered 'No (N)'	System	05 Sep 2020 17:03:15

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-05T13:03:12', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '78427212-8449-4879-906d-f8070abc8f03'	System	05 Sep 2020 17:03:15
User entered '05 Sep 2020 13:03'	System	05 Sep 2020 17:03:15

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 3'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-06T17:00:32', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'eb6740ff-0af2-490e-b82c-0fffb47a0d5b'	System	06 Sep 2020 21:01:04
User entered 'Yes (Y)'	System	06 Sep 2020 21:01:04

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-06T17:00:43', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'eb6740ff-0af2-490e-b82c-0fffb47a0d5b'	System	06 Sep 2020 21:01:04
User entered '98.6'	System	06 Sep 2020 21:01:04

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-06T17:00:47', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'eb6740ff-0af2-490e-b82c-0fffb47a0d5b'	System	06 Sep 2020 21:01:04
User entered 'No (N)'	System	06 Sep 2020 21:01:04

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-06T17:00:59', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'eb6740ff-0af2-490e-b82c-0fffb47a0d5b'	System	06 Sep 2020 21:01:04
User entered '06 Sep 2020 17:00'	System	06 Sep 2020 21:01:04

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 4'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-07T13:20:41', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'c4806377-450a-4231-b4da-dd1e033de11e'	System	07 Sep 2020 17:21:14
User entered 'Yes (Y)'	System	07 Sep 2020 17:21:14

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-07T13:20:59', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'c4806377-450a-4231-b4da-dd1e033de11e' User entered '98.7'	System	07 Sep 2020 17:21:14
	System	07 Sep 2020 17:21:14

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-07T13:21:04', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'c4806377-450a-4231-b4da-dd1e033de11e'	System	07 Sep 2020 17:21:14
User entered 'No (N)'	System	07 Sep 2020 17:21:14

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-07T13:21:10', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'c4806377-450a-4231-b4da-dd1e033de11e'	System	07 Sep 2020 17:21:14
User entered '07 Sep 2020 13:21'	System	07 Sep 2020 17:21:14

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 5'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-08T13:25:32', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'c0855a52-701d-4819-aa3d-a2cf0dd1e8dc'	System	08 Sep 2020 17:25:53
User entered 'Yes (Y)'	System	08 Sep 2020 17:25:53

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-08T13:25:41', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'c0855a52-701d-4819-aa3d-a2cf0dd1e8dc'	System	08 Sep 2020 17:25:53
User entered '97.8'	System	08 Sep 2020 17:25:53

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-08T13:25:45', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'c0855a52-701d-4819-aa3d-a2cf0dd1e8dc'	System	08 Sep 2020 17:25:53
User entered 'No (N)'	System	08 Sep 2020 17:25:53

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-08T13:25:48', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'c0855a52-701d-4819-aa3d-a2cf0dd1e8dc'	System	08 Sep 2020 17:25:53
User entered '08 Sep 2020 13:25'	System	08 Sep 2020 17:25:53

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 6'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-09T12:07:48', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '2130783b-21c1-4d6e-b9b1-c5ab0d76e524'	System	09 Sep 2020 16:08:08
User entered 'Yes (Y)'	System	09 Sep 2020 16:08:08

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-09T12:07:55', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '2130783b-21c1-4d6e-b9b1-c5ab0d76e524' User entered '98.2'	System	09 Sep 2020 16:08:08
	System	09 Sep 2020 16:08:08

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-09T12:08:00', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '2130783b-21c1-4d6e-b9b1-c5ab0d76e524'	System	09 Sep 2020 16:08:08
User entered 'No (N)'	System	09 Sep 2020 16:08:08

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-09T12:08:03', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '2130783b-21c1-4d6e-b9b1-c5ab0d76e524' User entered '09 Sep 2020 12:08'	System	09 Sep 2020 16:08:08
	System	09 Sep 2020 16:08:08

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 7'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-10T20:30:23', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '86f77b5f-e594-48d4-8610-07893b7bd754'	System	11 Sep 2020 00:30:46
User entered 'Yes (Y)'	System	11 Sep 2020 00:30:46

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-10T20:30:30', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '86f77b5f-e594-48d4-8610-07893b7bd754'	System	11 Sep 2020 00:30:46
User entered '98.4'	System	11 Sep 2020 00:30:46

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-10T20:30:35', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '86f77b5f-e594-48d4-8610-07893b7bd754'	System	11 Sep 2020 00:30:46
User entered 'No (N)'	System	11 Sep 2020 00:30:46

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-10T20:30:40', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '86f77b5f-e594-48d4-8610-07893b7bd754'	System	11 Sep 2020 00:30:46
User entered '10 Sep 2020 20:30'	System	11 Sep 2020 00:30:46

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:13

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 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T16:52:48', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'f56cc5cc-1620-4450-9217-efceaa79aaf0'	System	04 Sep 2020 20:53:16
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 20:53:16

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T16:52:55', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'f56cc5cc-1620-4450-9217-efceaa79aaf0'	System	04 Sep 2020 20:53:16
User entered 'No (N)'	System	04 Sep 2020 20:53:16

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T16:53:00', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'f56cc5cc-1620-4450-9217-efceaa79aaf0'	System	04 Sep 2020 20:53:16
User entered 'No (N)'	System	04 Sep 2020 20:53:16

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:13

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 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T16:53:07', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'f56cc5cc-1620-4450-9217-efceaa79aaf0'	System	04 Sep 2020 20:53:16
User entered 'None (1)'	System	04 Sep 2020 20:53:16

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T16:53:12', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'f56cc5cc-1620-4450-9217-efceaa79aaf0'	System	04 Sep 2020 20:53:16
User entered '04 Sep 2020 16:53'	System	04 Sep 2020 20:53:16

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '04 Sep 2020 16:38'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '04 Sep 2020 19:08'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:13

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 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T20:12:40', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'b588eef7-ada2-46a8-bf66-cdad9932bdad'	System	05 Sep 2020 00:13:01
User entered 'None (1)'	System	05 Sep 2020 00:13:01

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T20:12:43', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'b588eef7-ada2-46a8-bf66-cdad9932bdad'	System	05 Sep 2020 00:13:01
User entered 'No (N)'	System	05 Sep 2020 00:13:01

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T20:12:47', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'b588eef7-ada2-46a8-bf66-cdad9932bdad'	System	05 Sep 2020 00:13:01
User entered 'No (N)'	System	05 Sep 2020 00:13:01

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:13

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 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T20:12:52', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'b588eef7-ada2-46a8-bf66-cdad9932bdad'	System	05 Sep 2020 00:13:01
User entered 'None (1)'	System	05 Sep 2020 00:13:01

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T20:12:59', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'b588eef7-ada2-46a8-bf66-cdad9932bdad'	System	05 Sep 2020 00:13:01
User entered '04 Sep 2020 20:12'	System	05 Sep 2020 00:13:01

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '04 Sep 2020 20:03'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 2'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:13

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 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-05T13:03:19', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '1630f32c-1ad1-441c-9871-61b77560b2e1'	System	05 Sep 2020 17:03:40
User entered 'None (1)'	System	05 Sep 2020 17:03:40

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-05T13:03:23', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '1630f32c-1ad1-441c-9871-61b77560b2e1'	System	05 Sep 2020 17:03:40
User entered 'No (N)'	System	05 Sep 2020 17:03:40

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-05T13:03:29', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '1630f32c-1ad1-441c-9871-61b77560b2e1'	System	05 Sep 2020 17:03:40
User entered 'No (N)'	System	05 Sep 2020 17:03:40

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:13

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 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-05T13:03:33', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '1630f32c-1ad1-441c-9871-61b77560b2e1'	System	05 Sep 2020 17:03:40
User entered 'None (1)'	System	05 Sep 2020 17:03:40

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-05T13:03:36', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '1630f32c-1ad1-441c-9871-61b77560b2e1'	System	05 Sep 2020 17:03:40
User entered '05 Sep 2020 13:03'	System	05 Sep 2020 17:03:40

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 3'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:13

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 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-06T17:01:11', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '21edc182-8f82-46d3-96f5-025d9c6ec6d4'	System	06 Sep 2020 21:01:39
User entered 'None (1)'	System	06 Sep 2020 21:01:39

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-06T17:01:20', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '21edc182-8f82-46d3-96f5-025d9c6ec6d4'	System	06 Sep 2020 21:01:39
User entered 'No (N)'	System	06 Sep 2020 21:01:39

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-06T17:01:25', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '21edc182-8f82-46d3-96f5-025d9c6ec6d4'	System	06 Sep 2020 21:01:39
User entered 'No (N)'	System	06 Sep 2020 21:01:39

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:13

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 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-06T17:01:30', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '21edc182-8f82-46d3-96f5-025d9c6ec6d4'	System	06 Sep 2020 21:01:39
User entered 'None (1)'	System	06 Sep 2020 21:01:39

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-06T17:01:35', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '21edc182-8f82-46d3-96f5-025d9c6ec6d4'	System	06 Sep 2020 21:01:39
User entered '06 Sep 2020 17:01'	System	06 Sep 2020 21:01:39

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 4'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:13

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 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-07T13:21:15', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'ba626aa1-3637-48b5-8c33-545ef91b7de8'	System	07 Sep 2020 17:21:36
User entered 'None (1)'	System	07 Sep 2020 17:21:36

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-07T13:21:19', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'ba626aa1-3637-48b5-8c33-545ef91b7de8'	System	07 Sep 2020 17:21:36
User entered 'No (N)'	System	07 Sep 2020 17:21:36

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-07T13:21:22', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'ba626aa1-3637-48b5-8c33-545ef91b7de8'	System	07 Sep 2020 17:21:36
User entered 'No (N)'	System	07 Sep 2020 17:21:36

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:13

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 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-07T13:21:27', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'ba626aa1-3637-48b5-8c33-545ef91b7de8'	System	07 Sep 2020 17:21:36
User entered 'None (1)'	System	07 Sep 2020 17:21:36

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-07T13:21:31', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'ba626aa1-3637-48b5-8c33-545ef91b7de8'	System	07 Sep 2020 17:21:36
User entered '07 Sep 2020 13:21'	System	07 Sep 2020 17:21:36

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 5'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:13

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 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-08T13:25:54', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '7cae1991-bef9-4f23-8fb0-f8acbe01746a'	System	08 Sep 2020 17:26:10
User entered 'None (1)'	System	08 Sep 2020 17:26:10

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-08T13:25:57', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '7cae1991-bef9-4f23-8fb0-f8acbe01746a'	System	08 Sep 2020 17:26:10
User entered 'No (N)'	System	08 Sep 2020 17:26:10

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-08T13:26:00', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '7cae1991-bef9-4f23-8fb0-f8acbe01746a'	System	08 Sep 2020 17:26:10
User entered 'No (N)'	System	08 Sep 2020 17:26:10

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:13

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 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-08T13:26:03', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '7cae1991-bef9-4f23-8fb0-f8acbe01746a'	System	08 Sep 2020 17:26:10
User entered 'None (1)'	System	08 Sep 2020 17:26:10

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-08T13:26:06', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '7cae1991-bef9-4f23-8fb0-f8acbe01746a'	System	08 Sep 2020 17:26:10
User entered '08 Sep 2020 13:26'	System	08 Sep 2020 17:26:10

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 6'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:13

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 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-09T12:08:09', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '05062454-3ae4-4199-96b8-fa3444f26931'	System	09 Sep 2020 16:08:29
User entered 'None (1)'	System	09 Sep 2020 16:08:29

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-09T12:08:13', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '05062454-3ae4-4199-96b8-fa3444f26931'	System	09 Sep 2020 16:08:29
User entered 'No (N)'	System	09 Sep 2020 16:08:29

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-09T12:08:16', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '05062454-3ae4-4199-96b8-fa3444f26931'	System	09 Sep 2020 16:08:29
User entered 'No (N)'	System	09 Sep 2020 16:08:29

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:13

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 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-09T12:08:19', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '05062454-3ae4-4199-96b8-fa3444f26931'	System	09 Sep 2020 16:08:29
User entered 'None (1)'	System	09 Sep 2020 16:08:29

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-09T12:08:23', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '05062454-3ae4-4199-96b8-fa3444f26931'	System	09 Sep 2020 16:08:29
User entered '09 Sep 2020 12:08'	System	09 Sep 2020 16:08:29

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 7'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:13

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 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-10T20:30:45', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '9d35d241-deac-4537-b234-a4f923f1cf85'	System	11 Sep 2020 00:31:08
User entered 'None (1)'	System	11 Sep 2020 00:31:08

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-10T20:30:54', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '9d35d241-deac-4537-b234-a4f923f1cf85'	System	11 Sep 2020 00:31:08
User entered 'No (N)'	System	11 Sep 2020 00:31:08

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-10T20:30:58', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '9d35d241-deac-4537-b234-a4f923f1cf85'	System	11 Sep 2020 00:31:08
User entered 'No (N)'	System	11 Sep 2020 00:31:08

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:13

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 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-10T20:31:01', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '9d35d241-deac-4537-b234-a4f923f1cf85'	System	11 Sep 2020 00:31:08
User entered 'None (1)'	System	11 Sep 2020 00:31:08

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-10T20:31:04', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '9d35d241-deac-4537-b234-a4f923f1cf85'	System	11 Sep 2020 00:31:08
User entered '10 Sep 2020 20:31'	System	11 Sep 2020 00:31:08

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T16:54:47', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '2924b2c0-a0ee-4bcc-beec-8eaf08901591'	System	04 Sep 2020 20:55:10
User entered 'None (0)'	System	04 Sep 2020 20:55:10

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T16:54:53', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '2924b2c0-a0ee-4bcc-beec-8eaf08901591'	System	04 Sep 2020 20:55:10
User entered 'None (0)'	System	04 Sep 2020 20:55:10

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T16:54:58', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '2924b2c0-a0ee-4bcc-beec-8eaf08901591'	System	04 Sep 2020 20:55:10
User entered 'None (0)'	System	04 Sep 2020 20:55:10

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T16:54:10', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '2924b2c0-a0ee-4bcc-beec-8eaf08901591'	System	04 Sep 2020 20:55:10
User entered 'None (0)'	System	04 Sep 2020 20:55:10

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T16:53:57', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '2924b2c0-a0ee-4bcc-beec-8eaf08901591'	System	04 Sep 2020 20:55:10
User entered 'None (0)'	System	04 Sep 2020 20:55:10

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T16:54:14', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '2924b2c0-a0ee-4bcc-beec-8eaf08901591'	System	04 Sep 2020 20:55:10
User entered 'None (0)'	System	04 Sep 2020 20:55:10

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:13

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 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T16:54:27', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '2924b2c0-a0ee-4bcc-beec-8eaf08901591'	System	04 Sep 2020 20:55:10
User entered 'No (N)'	System	04 Sep 2020 20:55:10

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T16:55:07', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '2924b2c0-a0ee-4bcc-beec-8eaf08901591'	System	04 Sep 2020 20:55:10
User entered '04 Sep 2020 16:55'	System	04 Sep 2020 20:55:10

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '04 Sep 2020 16:38'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '04 Sep 2020 19:08'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T20:13:05', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '4b398103-bf77-4092-8805-146974e3d24f'	System	05 Sep 2020 00:13:46
User entered 'None (0)'	System	05 Sep 2020 00:13:46

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T20:13:09', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '4b398103-bf77-4092-8805-146974e3d24f'	System	05 Sep 2020 00:13:46
User entered 'None (0)'	System	05 Sep 2020 00:13:46

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T20:13:13', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '4b398103-bf77-4092-8805-146974e3d24f' User entered 'None (0)'	System	05 Sep 2020 00:13:46
	System	05 Sep 2020 00:13:46

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T20:13:16', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '4b398103-bf77-4092-8805-146974e3d24f' User entered 'None (0)'	System	05 Sep 2020 00:13:46
	System	05 Sep 2020 00:13:46

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T20:13:21', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '4b398103-bf77-4092-8805-146974e3d24f'	System	05 Sep 2020 00:13:46
User entered 'None (0)'	System	05 Sep 2020 00:13:46

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T20:13:25', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '4b398103-bf77-4092-8805-146974e3d24f'	System	05 Sep 2020 00:13:46
User entered 'None (0)'	System	05 Sep 2020 00:13:46

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:13

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 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T20:13:36', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '4b398103-bf77-4092-8805-146974e3d24f'	System	05 Sep 2020 00:13:46
User entered 'No (N)'	System	05 Sep 2020 00:13:46

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T20:13:41', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '4b398103-bf77-4092-8805-146974e3d24f'	System	05 Sep 2020 00:13:46
User entered '04 Sep 2020 20:13'	System	05 Sep 2020 00:13:46

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '04 Sep 2020 20:03'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 2'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-05T13:03:42', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'f53cd8bf-54fa-4105-81e4-a84542a723b3'	System	05 Sep 2020 17:04:12
User entered 'None (0)'	System	05 Sep 2020 17:04:12

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-05T13:03:45', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'f53cd8bf-54fa-4105-81e4-a84542a723b3'	System	05 Sep 2020 17:04:12
User entered 'None (0)'	System	05 Sep 2020 17:04:12

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-05T13:03:48', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'f53cd8bf-54fa-4105-81e4-a84542a723b3'	System	05 Sep 2020 17:04:12
User entered 'None (0)'	System	05 Sep 2020 17:04:12

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-05T13:03:52', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'f53cd8bf-54fa-4105-81e4-a84542a723b3'	System	05 Sep 2020 17:04:12
User entered 'None (0)'	System	05 Sep 2020 17:04:12

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-05T13:03:55', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'f53cd8bf-54fa-4105-81e4-a84542a723b3'	System	05 Sep 2020 17:04:12
User entered 'None (0)'	System	05 Sep 2020 17:04:12

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-05T13:03:57', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'f53cd8bf-54fa-4105-81e4-a84542a723b3'	System	05 Sep 2020 17:04:12
User entered 'None (0)'	System	05 Sep 2020 17:04:12

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:13

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 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-05T13:04:05', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'f53cd8bf-54fa-4105-81e4-a84542a723b3'	System	05 Sep 2020 17:04:12
User entered 'No (N)'	System	05 Sep 2020 17:04:12

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-05T13:04:09', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'f53cd8bf-54fa-4105-81e4-a84542a723b3'	System	05 Sep 2020 17:04:12
User entered '05 Sep 2020 13:04'	System	05 Sep 2020 17:04:12

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 3'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-06T17:01:50', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '94948479-deed-4432-bd10-3853e06feb4e'	System	06 Sep 2020 21:02:32
User entered 'None (0)'	System	06 Sep 2020 21:02:32

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-06T17:01:59', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '94948479-deed-4432-bd10-3853e06feb4e'	System	06 Sep 2020 21:02:32
User entered 'None (0)'	System	06 Sep 2020 21:02:32

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-06T17:02:03', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '94948479-deed-4432-bd10-3853e06feb4e'	System	06 Sep 2020 21:02:32
User entered 'None (0)'	System	06 Sep 2020 21:02:32

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-06T17:02:10', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '94948479-deed-4432-bd10-3853e06feb4e'	System	06 Sep 2020 21:02:32
User entered 'None (0)'	System	06 Sep 2020 21:02:32

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-06T17:02:13', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '94948479-deed-4432-bd10-3853e06feb4e'	System	06 Sep 2020 21:02:32
User entered 'None (0)'	System	06 Sep 2020 21:02:32

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-06T17:02:16', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '94948479-deed-4432-bd10-3853e06feb4e'	System	06 Sep 2020 21:02:32
User entered 'None (0)'	System	06 Sep 2020 21:02:32

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:13

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 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-06T17:02:23', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '94948479-deed-4432-bd10-3853e06feb4e'	System	06 Sep 2020 21:02:32
User entered 'No (N)'	System	06 Sep 2020 21:02:32

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-06T17:02:27', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '94948479-deed-4432-bd10-3853e06feb4e'	System	06 Sep 2020 21:02:32
User entered '06 Sep 2020 17:02'	System	06 Sep 2020 21:02:32

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 4'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-07T13:21:37', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '7778134d-1db3-4737-b3f8-0d288edfb992'	System	07 Sep 2020 17:22:05
User entered 'None (0)'	System	07 Sep 2020 17:22:05

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-07T13:21:40', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '7778134d-1db3-4737-b3f8-0d288edfb992'	System	07 Sep 2020 17:22:05
User entered 'None (0)'	System	07 Sep 2020 17:22:05

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-07T13:21:43', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '7778134d-1db3-4737-b3f8-0d288edfb992'	System	07 Sep 2020 17:22:05
User entered 'None (0)'	System	07 Sep 2020 17:22:05

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-07T13:21:46', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '7778134d-1db3-4737-b3f8-0d288edfb992'	System	07 Sep 2020 17:22:05
User entered 'None (0)'	System	07 Sep 2020 17:22:05

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-07T13:21:48', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '7778134d-1db3-4737-b3f8-0d288edfb992'	System	07 Sep 2020 17:22:05
User entered 'None (0)'	System	07 Sep 2020 17:22:05

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-07T13:21:51', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '7778134d-1db3-4737-b3f8-0d288edfb992'	System	07 Sep 2020 17:22:05
User entered 'None (0)'	System	07 Sep 2020 17:22:05

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:13

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 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-07T13:21:55', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '7778134d-1db3-4737-b3f8-0d288edfb992'	System	07 Sep 2020 17:22:05
User entered 'No (N)'	System	07 Sep 2020 17:22:05

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-07T13:22:02', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '7778134d-1db3-4737-b3f8-0d288edfb992'	System	07 Sep 2020 17:22:05
User entered '07 Sep 2020 13:22'	System	07 Sep 2020 17:22:05

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 5'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-08T13:26:12', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'd8936f63-ed40-4ca3-9f24-89781ed49892'	System	08 Sep 2020 17:26:33
User entered 'None (0)'	System	08 Sep 2020 17:26:33

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-08T13:26:14', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'd8936f63-ed40-4ca3-9f24-89781ed49892'	System	08 Sep 2020 17:26:33
User entered 'None (0)'	System	08 Sep 2020 17:26:33

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-08T13:26:16', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'd8936f63-ed40-4ca3-9f24-89781ed49892'	System	08 Sep 2020 17:26:33
User entered 'None (0)'	System	08 Sep 2020 17:26:33

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-08T13:26:18', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'd8936f63-ed40-4ca3-9f24-89781ed49892'	System	08 Sep 2020 17:26:33
User entered 'None (0)'	System	08 Sep 2020 17:26:33

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-08T13:26:20', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'd8936f63-ed40-4ca3-9f24-89781ed49892'	System	08 Sep 2020 17:26:33
User entered 'None (0)'	System	08 Sep 2020 17:26:33

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-08T13:26:23', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'd8936f63-ed40-4ca3-9f24-89781ed49892'	System	08 Sep 2020 17:26:33
User entered 'None (0)'	System	08 Sep 2020 17:26:33

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:13

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 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-08T13:26:26', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'd8936f63-ed40-4ca3-9f24-89781ed49892'	System	08 Sep 2020 17:26:33
User entered 'No (N)'	System	08 Sep 2020 17:26:33

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-08T13:26:29', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'd8936f63-ed40-4ca3-9f24-89781ed49892'	System	08 Sep 2020 17:26:33
User entered '08 Sep 2020 13:26'	System	08 Sep 2020 17:26:33

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 6'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-09T12:08:28', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'b18e4a1b-08e3-4440-9ece-5dbe5196f8d5'	System	09 Sep 2020 16:08:51
User entered 'None (0)'	System	09 Sep 2020 16:08:51

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-09T12:08:30', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'b18e4a1b-08e3-4440-9ece-5dbe5196f8d5'	System	09 Sep 2020 16:08:51
User entered 'None (0)'	System	09 Sep 2020 16:08:51

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-09T12:08:33', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'b18e4a1b-08e3-4440-9ece-5dbe5196f8d5'	System	09 Sep 2020 16:08:51
User entered 'None (0)'	System	09 Sep 2020 16:08:51

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-09T12:08:35', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'b18e4a1b-08e3-4440-9ece-5dbe5196f8d5'	System	09 Sep 2020 16:08:51
User entered 'None (0)'	System	09 Sep 2020 16:08:51

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-09T12:08:38', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'b18e4a1b-08e3-4440-9ece-5dbe5196f8d5'	System	09 Sep 2020 16:08:51
User entered 'None (0)'	System	09 Sep 2020 16:08:51

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-09T12:08:40', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'b18e4a1b-08e3-4440-9ece-5dbe5196f8d5'	System	09 Sep 2020 16:08:51
User entered 'None (0)'	System	09 Sep 2020 16:08:51

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:13

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 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-09T12:08:43', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'b18e4a1b-08e3-4440-9ece-5dbe5196f8d5'	System	09 Sep 2020 16:08:51
User entered 'No (N)'	System	09 Sep 2020 16:08:51

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-09T12:08:46', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'b18e4a1b-08e3-4440-9ece-5dbe5196f8d5'	System	09 Sep 2020 16:08:51
User entered '09 Sep 2020 12:08'	System	09 Sep 2020 16:08:51

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 7'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-10T20:31:10', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '5dca829f-f712-4509-a68f-240fe108fc69'	System	11 Sep 2020 00:31:31
User entered 'None (0)'	System	11 Sep 2020 00:31:31

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-10T20:31:14', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '5dca829f-f712-4509-a68f-240fe108fc69'	System	11 Sep 2020 00:31:31
User entered 'None (0)'	System	11 Sep 2020 00:31:31

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-10T20:31:16', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '5dca829f-f712-4509-a68f-240fe108fc69'	System	11 Sep 2020 00:31:31
User entered 'None (0)'	System	11 Sep 2020 00:31:31

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-10T20:31:18', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '5dca829f-f712-4509-a68f-240fe108fc69'	System	11 Sep 2020 00:31:31
User entered 'None (0)'	System	11 Sep 2020 00:31:31

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-10T20:31:21', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '5dca829f-f712-4509-a68f-240fe108fc69'	System	11 Sep 2020 00:31:31
User entered 'None (0)'	System	11 Sep 2020 00:31:31

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-10T20:31:23', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '5dca829f-f712-4509-a68f-240fe108fc69'	System	11 Sep 2020 00:31:31
User entered 'None (0)'	System	11 Sep 2020 00:31:31

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:13

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 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-10T20:31:26', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '5dca829f-f712-4509-a68f-240fe108fc69'	System	11 Sep 2020 00:31:31
User entered 'No (N)'	System	11 Sep 2020 00:31:31

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-10T20:31:29', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '5dca829f-f712-4509-a68f-240fe108fc69'	System	11 Sep 2020 00:31:31
User entered '10 Sep 2020 20:31'	System	11 Sep 2020 00:31:31

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

US3542168

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:28:58
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	16 Sep 2020 18:42:25

US3542168

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:28:58
User entered '14 Sep 2020'	Madhu Balachandran (b) (4)	16 Sep 2020 18:42:25

US3542168

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:28:58
User entered 'Contact Not Made (CONTACT NOT MADE)'	Madhu Balachandran (b) (4)	16 Sep 2020 18:42:25

US3542168

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4) (b) (4)	17 Sep 2020 04:28:58
User entered 'Called 5 times in 2 days. Unable to leave voicemail.'	Madhu Balachandran (b) (4)	16 Sep 2020 18:42:25

US3542168

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:28:58
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	16 Sep 2020 18:45:29

US3542168

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered 'l'	System	16 Sep 2020 18:45:29

US3542168

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4)	03 Nov 2020 21:24:13
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 18:36:13

US3542168

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered '18 Sep 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 18:36:13

US3542168

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 18:36:13

US3542168

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4)	03 Nov 2020 21:24:13
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 18:36:13

US3542168

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 15:05:56

US3542168

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered 'l'	System	30 Sep 2020 15:05:56

US3542168

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 15:06:09

US3542168

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '25 Sep 2020'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 15:06:09

US3542168

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 15:06:09

US3542168

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 15:06:09

US3542168

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:17:01
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	09 Oct 2020 15:36:51
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Erika Faust (b) (4)	09 Oct 2020 15:36:51
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	(b) (4)	
	Taylor Ladson (b) (4)	30 Sep 2020 15:06:14
	(b) (4)	

US3542168

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered 'l'	System	09 Oct 2020 15:36:51
User entered empty.	System	30 Sep 2020 15:06:14

US3542168

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:17:01
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:37:13

US3542168

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:13

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:17:01
User entered '8 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:37:13

US3542168

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:13

[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 07:43:23
User signature succeeded.	David Diemert (u) (4)	16 Oct 2020 04:17:01
User entered 'Clinic (Clinic)'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:37:13

US3542168

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered 'VISIT2'	System	09 Oct 2020 15:37:13

US3542168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User accepted default value 'Pre-Dose (PREDOSE)'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

US3542168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4)	16 Oct 2020 04:17:01
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	09 Oct 2020 17:48:19

US3542168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:17:01
User entered '8 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

US3542168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:17:01
User entered '10:47'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

US3542168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered '8 Oct 2020 10:47'	System	09 Oct 2020 17:48:19

US3542168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:17:01
User entered '98.4' F	Erika Faust (b) (4)	09 Oct 2020 17:48:19

US3542168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:17:01
User entered 'Oral (Oral)'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

US3542168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:17:01
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

US3542168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4)	16 Oct 2020 04:17:01
User entered '73'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

US3542168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered 'bpm'	System	09 Oct 2020 17:48:19

US3542168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4)	16 Oct 2020 04:17:01
User entered '16'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

US3542168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered 'breaths/min'	System	09 Oct 2020 17:48:19

US3542168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4)	16 Oct 2020 04:17:01
User entered '125'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

US3542168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered 'mmHg'	System	09 Oct 2020 17:48:19

US3542168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4)	16 Oct 2020 04:17:01
User entered '92'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

US3542168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered 'mmHg'	System	09 Oct 2020 17:48:19

US3542168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User accepted default value 'Post-Dose (POSTDOSE)'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

US3542168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:17:01
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

US3542168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:17:01
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

US3542168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:17:01
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

US3542168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered empty.	System	09 Oct 2020 17:48:19

US3542168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:17:01
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

US3542168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:17:01
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

US3542168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:17:01
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

US3542168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4)	16 Oct 2020 04:17:01
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

US3542168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered empty.	System	09 Oct 2020 17:48:19

US3542168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4)	16 Oct 2020 04:17:01
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

US3542168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered empty.	System	09 Oct 2020 17:48:19

US3542168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4) (b) (4)	16 Oct 2020 04:17:01
User entered empty.	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

US3542168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered empty.	System	09 Oct 2020 17:48:19

US3542168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4)	16 Oct 2020 04:17:01
User entered empty.	(b) (4) Erika Faust (b) (4)	09 Oct 2020 17:48:19

US3542168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered empty.	System	09 Oct 2020 17:48:19

US3542168

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:17:01
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:37:21

US3542168

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:17:01
User entered '8 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:37:21

US3542168

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:17:01
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:47:10

US3542168

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User closed query 'Per CDM: Please update the Study Discontinuation form accordingly if the subject was not given the study drug due to AE.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 07:01:12
Query 'Per CDM: Please update the Study Discontinuation form accordingly if the subject was not given the study drug due to AE.' answered with 'Dosing discontinuation form updated' (Site from DM).	Hannah Yellin (b) (4) (b) (4)	19 Oct 2020 19:33:16
User opened query 'Per CDM: Please update the Study Discontinuation form accordingly if the subject was not given the study drug due to AE.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 04:05:31
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:47:10

US3542168

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

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 07:43:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:17:01
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:47:10

US3542168

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered empty.	System	09 Oct 2020 17:47:10

US3542168

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:17:01
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:47:10

US3542168

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:17:01
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:47:10

US3542168

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered empty.	System	09 Oct 2020 17:47:10

US3542168

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:17:01
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:47:10

US3542168

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered empty.	System	09 Oct 2020 17:47:10

US3542168

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered empty.	System	09 Oct 2020 17:47:10

US3542168

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:17:01
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	09 Oct 2020 17:48:34

US3542168

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:13

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:17:01
User entered '8 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:34

US3542168

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:13

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:17:01
User entered '11:40'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:34

US3542168

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered '8 Oct 2020 11:40'	System	09 Oct 2020 17:48:34

US3542168

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:08:13

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:17:01
User entered '8 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:49:02

US3542168

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:08:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:49:02

US3542168

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:08:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:17:01
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:49:02

US3542168

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:08:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:17:01
User entered '11:15'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:49:02

US3542168

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered '8 Oct 2020 11:15'	System	09 Oct 2020 17:49:02

US3542168

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:08:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:49:02

US3542168

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:08:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:17:01
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:49:02

US3542168

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:08:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:17:01
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:49:02

US3542168

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered empty.	System	09 Oct 2020 17:49:02

US3542168

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 04:17:01
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	09 Oct 2020 17:49:11

US3542168

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered 'I'	System	09 Oct 2020 17:49:11

US3542168

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:46:00
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	16 Oct 2020 19:31:43

US3542168

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:46:00
User entered '15 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	16 Oct 2020 19:31:43

US3542168

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:46:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4)	16 Oct 2020 19:31:43

US3542168

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4)	21 Oct 2020 18:46:00
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	16 Oct 2020 19:31:43

US3542168

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4)	21 Oct 2020 18:46:00
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	16 Oct 2020 19:31:47

US3542168

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered 'l'	System	16 Oct 2020 19:31:47

US3542168

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:28:16
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	23 Oct 2020 16:35:02

US3542168

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:28:16
User entered '22 Oct 2020'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	23 Oct 2020 16:35:02

US3542168

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:28:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	23 Oct 2020 16:35:02

US3542168

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4)	30 Oct 2020 01:28:16
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	23 Oct 2020 16:35:02

US3542168

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4)	30 Oct 2020 01:28:16
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	23 Oct 2020 16:35:07

US3542168

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered 'l'	System	23 Oct 2020 16:35:07

US3542168

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	31 Oct 2020 18:33:49
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	30 Oct 2020 16:18:37

US3542168

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	31 Oct 2020 18:33:49
User entered '29 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	30 Oct 2020 16:18:37

US3542168

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	31 Oct 2020 18:33:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4) (b) (4)	30 Oct 2020 16:18:37

US3542168

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4)	31 Oct 2020 18:33:49
User entered empty.	(b) (4) Erika Faust (b) (4)	30 Oct 2020 16:18:37

US3542168

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4)	31 Oct 2020 18:33:49
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	30 Oct 2020 16:18:41

US3542168

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered 'l'	System	30 Oct 2020 16:18:41

US3542168

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:22:55

US3542168

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
User entered '12 Nov 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:22:55

US3542168

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:13

[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 07:43:23
User signature succeeded.	David Diemert (u) (4)	20 Nov 2020 04:15:40
User entered 'Clinic (Clinic)'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:22:55

US3542168

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered 'VISIT3'	System	13 Nov 2020 17:22:55

US3542168

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4)	20 Nov 2020 04:15:40
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:28:53

US3542168

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
User entered '12 Nov 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:28:53

US3542168

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
User entered '12:56'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:28:53

US3542168

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered '12 Nov 2020 12:56'	System	13 Nov 2020 17:28:53

US3542168

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4)	20 Nov 2020 04:15:40
User entered '98.5' F	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:28:53

US3542168

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
User entered 'Oral (Oral)'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:28:53

US3542168

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:28:53

US3542168

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4)	20 Nov 2020 04:15:40
User entered '58'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:28:53

US3542168

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered 'bpm'	System	13 Nov 2020 17:28:53

US3542168

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4)	20 Nov 2020 04:15:40
User entered '17'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:28:53

US3542168

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered 'breaths/min'	System	13 Nov 2020 17:28:53

US3542168

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4)	20 Nov 2020 04:15:40
User entered '138'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:28:53

US3542168

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered 'mmHg'	System	13 Nov 2020 17:28:53

US3542168

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4)	20 Nov 2020 04:15:40
User entered '76'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:28:53

US3542168

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered 'mmHg'	System	13 Nov 2020 17:28:53

US3542168

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23

US3542168

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23

US3542168

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:22:46

US3542168

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
User entered '12 Nov 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:22:46

US3542168

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:22:33

US3542168

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:13

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
User entered '12 Nov 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:22:33

US3542168

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:13

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
User entered '12:57'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:22:33

US3542168

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered '12 Nov 2020 12:57'	System	13 Nov 2020 17:22:33

US3542168

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4)	20 Nov 2020 04:15:40
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:22:13

US3542168

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered 'l'	System	13 Nov 2020 17:22:13

US3542168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 92'	System	04 Sep 2020 20:20:50

US3542168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-12-02T09:10:27', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '65f9311c-983a-4109-9fb3-014791466619'	System	02 Dec 2020 14:10:44
User entered 'No (N)'	System	02 Dec 2020 14:10:44

US3542168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-12-02T09:10:31', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '65f9311c-983a-4109-9fb3-014791466619'	System	02 Dec 2020 14:10:44
User entered 'No (N)'	System	02 Dec 2020 14:10:44

US3542168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-12-02T09:10:40', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '65f9311c-983a-4109-9fb3-014791466619' User entered '02 Dec 2020 09:10:40'	System	02 Dec 2020 14:10:44
	System	02 Dec 2020 14:10:44

US3542168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '02 Dec 2020 00:01'	System	04 Sep 2020 20:20:50

US3542168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '06 Dec 2020 23:59'	System	04 Sep 2020 20:20:50

US3542168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 99'	System	04 Sep 2020 20:20:50

US3542168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-12-09T10:08:04', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'a11b0c27-ca72-48f1-8d7f-7e969ed1999a'	System	09 Dec 2020 15:08:19
User entered 'No (N)'	System	09 Dec 2020 15:08:19

US3542168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-12-09T10:08:09', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'a11b0c27-ca72-48f1-8d7f-7e969ed1999a'	System	09 Dec 2020 15:08:19
User entered 'No (N)'	System	09 Dec 2020 15:08:19

US3542168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-12-09T10:08:14', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'a11b0c27-ca72-48f1-8d7f-7e969ed1999a' User entered '09 Dec 2020 10:08:14'	System	09 Dec 2020 15:08:19
	System	09 Dec 2020 15:08:19

US3542168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '09 Dec 2020 00:01'	System	04 Sep 2020 20:20:50

US3542168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '13 Dec 2020 23:59'	System	04 Sep 2020 20:20:50

US3542168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 106'	System	04 Sep 2020 20:20:50

US3542168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-12-16T09:33:16', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '9ca2163a-eabb-4063-90ab-0d841c7d8406'	System	16 Dec 2020 14:33:50
User entered 'No (N)'	System	16 Dec 2020 14:33:50

US3542168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-12-16T09:33:37', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '9ca2163a-eabb-4063-90ab-0d841c7d8406'	System	16 Dec 2020 14:33:50
User entered 'No (N)'	System	16 Dec 2020 14:33:50

US3542168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-12-16T09:33:42', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '9ca2163a-eabb-4063-90ab-0d841c7d8406'	System	16 Dec 2020 14:33:50
User entered '16 Dec 2020 09:33:42'	System	16 Dec 2020 14:33:50

US3542168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '16 Dec 2020 00:01'	System	04 Sep 2020 20:20:50

US3542168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '20 Dec 2020 23:59'	System	04 Sep 2020 20:20:50

US3542168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 113'	System	04 Sep 2020 20:20:50

US3542168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-12-23T09:43:15', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'dc01adc0-45b1-49c9-b785-a58211fccaec'	System	23 Dec 2020 14:43:28
User entered 'No (N)'	System	23 Dec 2020 14:43:28

US3542168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-12-23T09:43:19', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'dc01adc0-45b1-49c9-b785-a58211fccaec'	System	23 Dec 2020 14:43:28
User entered 'No (N)'	System	23 Dec 2020 14:43:28

US3542168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-12-23T09:43:24', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'dc01adc0-45b1-49c9-b785-a58211fccaec'	System	23 Dec 2020 14:43:28
User entered '23 Dec 2020 09:43:24'	System	23 Dec 2020 14:43:28

US3542168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '23 Dec 2020 00:01'	System	04 Sep 2020 20:20:50

US3542168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:09:30
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '27 Dec 2020 23:59'	System	04 Sep 2020 20:20:50

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 82'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '22 Nov 2020 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '26 Nov 2020 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 89'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '29 Nov 2020 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '03 Dec 2020 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 96'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '06 Dec 2020 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '10 Dec 2020 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 103'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '13 Dec 2020 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '17 Dec 2020 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 110'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '20 Dec 2020 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '24 Dec 2020 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 117'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '27 Dec 2020 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '31 Dec 2020 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 124'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '03 Jan 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '07 Jan 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 131'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '10 Jan 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '14 Jan 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 138'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '17 Jan 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '21 Jan 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 145'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '24 Jan 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '28 Jan 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 152'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '31 Jan 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '04 Feb 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 159'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '07 Feb 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '11 Feb 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 166'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '14 Feb 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '18 Feb 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 173'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '21 Feb 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '25 Feb 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 180'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '28 Feb 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '04 Mar 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 187'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '07 Mar 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '11 Mar 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 194'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '14 Mar 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '18 Mar 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 201'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '21 Mar 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '25 Mar 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 208'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '28 Mar 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '01 Apr 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 215'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '04 Apr 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '08 Apr 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 222'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '11 Apr 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '15 Apr 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 229'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '18 Apr 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '22 Apr 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 236'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '25 Apr 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '29 Apr 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 243'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '02 May 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '06 May 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 250'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '09 May 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '13 May 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 257'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '16 May 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '20 May 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 264'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '23 May 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '27 May 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 271'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '30 May 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '03 Jun 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 278'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '06 Jun 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '10 Jun 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 285'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '13 Jun 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '17 Jun 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 292'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '20 Jun 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '24 Jun 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 299'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '27 Jun 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '01 Jul 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 306'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '04 Jul 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '08 Jul 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 313'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '11 Jul 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '15 Jul 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 320'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '18 Jul 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '22 Jul 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 327'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '25 Jul 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '29 Jul 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 334'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '01 Aug 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '05 Aug 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 341'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '08 Aug 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '12 Aug 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 348'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '15 Aug 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '19 Aug 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 355'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '22 Aug 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '26 Aug 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 362'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '29 Aug 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '02 Sep 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 369'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '05 Sep 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '09 Sep 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 376'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '12 Sep 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '16 Sep 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 383'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '19 Sep 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '23 Sep 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 390'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '26 Sep 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '30 Sep 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 397'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '03 Oct 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '07 Oct 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 404'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '10 Oct 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '14 Oct 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 411'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '17 Oct 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '21 Oct 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 418'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '24 Oct 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '28 Oct 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 425'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '31 Oct 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '04 Nov 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 432'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '07 Nov 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '11 Nov 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 439'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '14 Nov 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '18 Nov 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 446'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '21 Nov 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '25 Nov 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 453'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '28 Nov 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '02 Dec 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 460'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '05 Dec 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '09 Dec 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 467'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '12 Dec 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '16 Dec 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 474'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '19 Dec 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '23 Dec 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 481'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '26 Dec 2021 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '30 Dec 2021 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 488'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '02 Jan 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '06 Jan 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 495'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '09 Jan 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '13 Jan 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 502'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '16 Jan 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '20 Jan 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 509'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '23 Jan 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '27 Jan 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 516'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '30 Jan 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '03 Feb 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 523'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '06 Feb 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '10 Feb 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 530'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '13 Feb 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '17 Feb 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 537'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '20 Feb 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '24 Feb 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 544'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '27 Feb 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '03 Mar 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 551'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '06 Mar 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '10 Mar 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 558'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '13 Mar 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '17 Mar 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 565'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '20 Mar 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '24 Mar 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 572'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '27 Mar 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '31 Mar 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 579'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '03 Apr 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '07 Apr 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 586'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '10 Apr 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '14 Apr 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 593'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '17 Apr 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '21 Apr 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 600'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '24 Apr 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '28 Apr 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 607'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '01 May 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '05 May 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 614'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '08 May 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '12 May 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 621'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '15 May 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '19 May 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 628'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '22 May 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '26 May 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 635'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '29 May 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '02 Jun 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 642'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '05 Jun 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '09 Jun 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 649'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '12 Jun 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '16 Jun 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 656'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '19 Jun 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '23 Jun 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 663'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '26 Jun 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '30 Jun 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 670'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '03 Jul 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '07 Jul 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 677'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '10 Jul 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '14 Jul 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 684'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '17 Jul 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '21 Jul 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 691'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '24 Jul 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '28 Jul 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 698'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '31 Jul 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '04 Aug 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 705'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '07 Aug 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '11 Aug 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 712'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '14 Aug 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '18 Aug 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 719'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '21 Aug 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '25 Aug 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 726'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '28 Aug 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '01 Sep 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 733'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '04 Sep 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '08 Sep 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 740'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '11 Sep 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '15 Sep 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 747'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '18 Sep 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '22 Sep 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 754'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '25 Sep 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '29 Sep 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 761'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '02 Oct 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '06 Oct 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 768'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '09 Oct 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '13 Oct 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 775'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '16 Oct 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '20 Oct 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 782'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '23 Oct 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '27 Oct 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 789'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '30 Oct 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '03 Nov 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered 'Day 796'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '06 Nov 2022 00:01'	System	18 Feb 2021 16:20:49

US3542168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Feb 2021 16:20:49
User entered '10 Nov 2022 23:59'	System	18 Feb 2021 16:20:49

US3542168

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:08:36
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	02 Dec 2020 17:28:17

US3542168

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:08:36
User entered '02 Dec 2020' reason for change: Data Entry Error	Madhu Balachandran (b) (4)	02 Dec 2020 17:40:39
User entered '2 Dec 2020'	Madhu Balachandran (b) (4)	02 Dec 2020 17:28:17

US3542168

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:08:36
User entered 'Contact Made (CONTACT MADE)'	Madhu Balachandran (b) (4)	02 Dec 2020 17:28:17

US3542168

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (u) (4) (b) (4)	10 Dec 2020 16:08:36
User entered empty.	Madhu Balachandran (b) (4)	02 Dec 2020 17:28:17

US3542168

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:08:36
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	02 Dec 2020 17:28:19

US3542168

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:43:23
User entered 'I'	System	02 Dec 2020 17:28:19

US3542168

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:45:28
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Jan 2021 14:26:58

US3542168

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:45:28
User entered '05 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Jan 2021 14:26:58

US3542168

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:45:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Jan 2021 14:26:58

US3542168

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:45:28
User entered empty.	(b) (4) Erika Faust (b) (4)	11 Jan 2021 14:26:58

US3542168

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:45:28
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	11 Jan 2021 14:27:02

US3542168

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User entered 'l'	System	11 Jan 2021 14:27:02

US3542168

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:42:13

US3542168

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered '05 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:42:13

US3542168

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:42:13

US3542168

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered empty.	(b) (4) Erika Faust (b) (4)	08 Feb 2021 17:42:13

US3542168

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:42:18

US3542168

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User entered 'l'	System	08 Feb 2021 17:42:18

US3542168

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:07
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:23:09

US3542168

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:07
User entered '08 Mar 2021'	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:23:09
	(b) (4)	

US3542168

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:23:09

US3542168

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:07
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	09 Mar 2021 16:23:09

US3542168

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:07
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	09 Mar 2021 16:23:15

US3542168

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User entered 'l'	System	09 Mar 2021 16:23:15

US3542168

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 18:20:29

US3542168

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:12
User entered '01 Apr 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:20:29

US3542168

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:12
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:20:29

US3542168

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User entered 'VISIT4'	System	01 Apr 2021 18:20:29

US3542168

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:20:39

US3542168

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:12
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 18:20:39

US3542168

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:20:39

US3542168

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User entered empty.	System	01 Apr 2021 18:20:39

US3542168

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:12
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 18:20:39

US3542168

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:20:39

US3542168

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:20:39

US3542168

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:20:39

US3542168

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User entered empty.	System	01 Apr 2021 18:20:39

US3542168

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:20:39

US3542168

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User entered empty.	System	01 Apr 2021 18:20:39

US3542168

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:12
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 18:20:39

US3542168

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User entered empty.	System	01 Apr 2021 18:20:39

US3542168

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:12
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 18:20:39

US3542168

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User entered empty.	System	01 Apr 2021 18:20:39

US3542168

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51

US3542168

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51

US3542168

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:20:53

US3542168

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:13

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:20:53

US3542168

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 18:21:10

US3542168

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:13

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:12
User entered '01 Apr 2021'	(b) (4), (b) (6)	01 Apr 2021 18:21:10

US3542168

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:13

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:12
User entered '10:35'	(b) (4), (b) (6)	01 Apr 2021 18:21:10

US3542168

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User entered '01 Apr 2021 10:35'	System	01 Apr 2021 18:21:10

US3542168

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 18:21:20

US3542168

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:08:51
User entered 'I'	System	01 Apr 2021 18:21:20

US3542168

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

Form: Visit Date

Generated On: 10 Jun 2021 08:08:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	08 Feb 2021 17:19:13

US3542168

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

Form: Visit Date

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered '05 Feb 2021'	(b) (4) Erika Faust (b) (4)	08 Feb 2021 17:19:13

US3542168

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

Form: Visit Date

Generated On: 10 Jun 2021 08:08:13

[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 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered 'Clinic (Clinic)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:19:13

US3542168

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

Form: Visit Date

Generated On: 10 Jun 2021 08:08:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered 'UNBLND_DECIDE'	System	08 Feb 2021 17:19:13

US3542168

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

Form: Unblinding

Generated On: 10 Jun 2021 08:08:13

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered '05 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:19:52

US3542168

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

Form: Unblinding

Generated On: 10 Jun 2021 08:08:13

[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 18:03:50
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:45:16
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:26:29

US3542168

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

Form: Unblinding

Generated On: 10 Jun 2021 08:08:13

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	08 Feb 2021 17:19:52

US3542168

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

Form: Unblinding

Generated On: 10 Jun 2021 08:08:13

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:45:16
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:26:29

US3542168

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

Form: Unblinding

Generated On: 10 Jun 2021 08:08:13

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered '05 Feb 2021'	(b) (4) Erika Faust (b) (4)	08 Feb 2021 17:19:52

US3542168

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

Form: Unblinding

Generated On: 10 Jun 2021 08:08:13

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered 'Placebo (Placebo)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:19:52

US3542168

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

Form: Unblinding

Generated On: 10 Jun 2021 08:08:13

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered 'Placebo (Placebo)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:19:52

US3542168

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

Form: Unblinding

Generated On: 10 Jun 2021 08:08:13

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered 'Placebo (Placebo)'	(b) (4) Erika Faust (b) (4)	08 Feb 2021 17:19:52

US3542168

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

Form: Unblinding

Generated On: 10 Jun 2021 08:08:13

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	08 Feb 2021 17:19:52

US3542168

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

Form: Unblinding

Generated On: 10 Jun 2021 08:08:13

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered 'I'	System	08 Feb 2021 17:19:52

US3542168

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

Form: Unblinding

Generated On: 10 Jun 2021 08:08:13

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered 'I'	System	08 Feb 2021 17:19:52

US3542168

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4)	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4)	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:13

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered empty.	System	08 Feb 2021 17:21:39
DataPoint set to visible.	System	08 Feb 2021 17:19:52

US3542168

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4)	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4)	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:13

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered empty.	System	08 Feb 2021 17:21:39
DataPoint set to visible.	System	08 Feb 2021 17:19:52

US3542168

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User accepted default value 'Pre-Dose (PREDOSE)'	Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered '05 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered '12:34'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered '05 Feb 2021 12:34'	System	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered '98.9' F	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered 'Oral (Oral)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered empty.	(b) (4) Erika Faust (b) (4)	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered '60'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered 'bpm'	System	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered '16'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered 'breaths/min'	System	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered '143'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered 'mmHg'	System	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered '95'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered 'mmHg'	System	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4)	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4)	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:13

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered empty.	System	08 Feb 2021 17:21:39
DataPoint set to visible.	System	08 Feb 2021 17:19:52

US3542168

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User accepted default value 'Post-Dose (POSTDOSE)'	Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered '05 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered '13:37'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered '05 Feb 2021 13:37'	System	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered '98.1' F	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered 'Oral (Oral)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered '57'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered 'bpm'	System	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered '16'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered 'breaths/min'	System	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered '161'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered 'mmHg'	System	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered '93'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:21:39

US3542168

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered 'mmHg'	System	08 Feb 2021 17:21:39

US3542168

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

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:20:29

US3542168

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

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:13

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered '05 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:20:29

US3542168

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

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	08 Feb 2021 17:20:44

US3542168

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

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:20:44

US3542168

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

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

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 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered empty.	(b) (4) Erika Faust (b) (4)	08 Feb 2021 17:20:44

US3542168

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

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered 'mRNA-1273'	System	08 Feb 2021 17:20:44
DataPoint set to visible.	System	08 Feb 2021 17:19:52

US3542168

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

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered '05 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:20:44

US3542168

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

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered '13:05'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:20:44

US3542168

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

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered '05 Feb 2021 13:05'	System	08 Feb 2021 17:20:44

US3542168

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

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:20:44

US3542168

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

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered 'ONCE'	System	08 Feb 2021 17:20:44

US3542168

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

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered 'INTRAMUSCULAR'	System	08 Feb 2021 17:20:44

US3542168

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	08 Feb 2021 17:19:24

US3542168

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:13

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered '05 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:19:24

US3542168

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:13

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered '12:29'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:19:24

US3542168

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered '05 Feb 2021 12:29'	System	08 Feb 2021 17:19:24

US3542168

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:08:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:19:35

US3542168

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:08:13

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered '05 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:19:35

US3542168

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:08:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered '12:33'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Feb 2021 17:19:35

US3542168

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered '05 Feb 2021 12:33'	System	08 Feb 2021 17:19:35

US3542168

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

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	08 Feb 2021 17:20:17

US3542168

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

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered 'I'	System	08 Feb 2021 17:20:17

US3542168

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:52
User signature succeeded.	David Diemert (b) (4)	17 Feb 2021 04:03:53
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4)	16 Feb 2021 20:37:06

US3542168

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:52
User signature succeeded.	David Diemert (b) (4)	17 Feb 2021 04:03:53
User entered '12 Feb 2021'	(b) (4) Hannah Yellin (b) (4) (b) (4)	16 Feb 2021 20:37:06

US3542168

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:52
User signature succeeded.	David Diemert (b) (4)	17 Feb 2021 04:03:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Hannah Yellin (b) (4)	16 Feb 2021 20:37:06

US3542168

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:52
User signature succeeded.	David Diemert (b) (4)	17 Feb 2021 04:03:53
User entered empty.	(b) (4) Hannah Yellin (b) (4)	16 Feb 2021 20:37:06
	(b) (4)	

US3542168

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	17 Feb 2021 04:03:53
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4)	16 Feb 2021 20:37:15
	(b) (4)	

US3542168

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered 'l'	System	16 Feb 2021 20:37:15

US3542168

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered 'I'	System	16 Feb 2021 20:37:15
DataPoint set to visible.	System	16 Feb 2021 20:37:15

US3542168

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:07
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:19:34

US3542168

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:07
User entered '08 Mar 2021'	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:19:34
	(b) (4)	

US3542168

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:13

[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 18:03:50
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:07
User entered 'Clinic (Clinic)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	09 Mar 2021 16:19:34

US3542168

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered 'OLD29'	System	09 Mar 2021 16:19:34

US3542168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User accepted default value 'Pre-Dose (PREDOSE)'	Taylor Ladson (b) (4) (b) (4)	09 Mar 2021 16:20:30

US3542168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:07
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:20:30

US3542168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:07
User entered '08 Mar 2021'	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:20:30
	(b) (4)	

US3542168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:07
User entered '12:34'	(b) (4) Taylor Ladson (b) (4) (b) (4)	09 Mar 2021 16:20:30

US3542168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered '08 Mar 2021 12:34'	System	09 Mar 2021 16:20:30

US3542168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:07
User entered '98' F	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:20:30

US3542168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:07
User entered 'Oral (Oral)'	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:20:30

US3542168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:07
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	09 Mar 2021 16:20:30

US3542168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:07
User entered '60'	(b) (4) Taylor Ladson (b) (4) (b) (4)	09 Mar 2021 16:20:30

US3542168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered 'bpm'	System	09 Mar 2021 16:20:30

US3542168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:07
User entered '17'	(b) (4) Taylor Ladson (b) (4) (b) (4)	09 Mar 2021 16:20:30

US3542168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered 'breaths/min'	System	09 Mar 2021 16:20:30

US3542168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:07
User entered '166'	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:20:30

US3542168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered 'mmHg'	System	09 Mar 2021 16:20:30

US3542168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:07
User entered '97'	(b) (4) Taylor Ladson (b) (4) (b) (4)	09 Mar 2021 16:20:30

US3542168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered 'mmHg'	System	09 Mar 2021 16:20:30

US3542168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50

US3542168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50

US3542168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50

US3542168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50

US3542168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50

US3542168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50

US3542168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50

US3542168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50

US3542168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50

US3542168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50

US3542168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50

US3542168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50

US3542168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50

US3542168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50

US3542168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50

US3542168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50

US3542168

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:07
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:19:43

US3542168

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:13

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:07
User entered '08 Mar 2021'	(b) (4) Taylor Ladson (b) (4) (b) (4)	09 Mar 2021 16:19:43

US3542168

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:07
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:21:15

US3542168

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:07
User entered empty.	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:21:15
	(b) (4)	

US3542168

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

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 18:03:50
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:07
User entered empty.	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:21:15
	(b) (4)	

US3542168

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered 'mRNA-1273'	System	09 Mar 2021 16:21:15
DataPoint set to visible.	System	16 Feb 2021 20:37:15

US3542168

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:07
User entered '08 Mar 2021'	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:21:15
	(b) (4)	

US3542168

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:07
User entered '12:50'	(b) (4) Taylor Ladson (b) (4) (b) (4)	09 Mar 2021 16:21:15

US3542168

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered '08 Mar 2021 12:50'	System	09 Mar 2021 16:21:15

US3542168

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4), (b) (6)	11 Mar 2021 04:45:05
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:07
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered with 'Participant reported arm pain since first OL vaccine, added to PD log.' (Site from System).	(b) (4)	
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	Taylor Ladson (b) (4)	09 Mar 2021 16:22:01
User entered 'Left Arm (LEFT ARM)'	(b) (4)	
	System	09 Mar 2021 16:21:15
	Taylor Ladson (b) (4)	09 Mar 2021 16:21:15
	(b) (4)	

US3542168

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered 'ONCE'	System	09 Mar 2021 16:21:15

US3542168

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered 'INTRAMUSCULAR'	System	09 Mar 2021 16:21:15

US3542168

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:13:07
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:19:48

US3542168

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered 'l'	System	09 Mar 2021 16:19:48

US3542168

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:18:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Mar 2021 18:00:53

US3542168

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:18:34
User entered '15 Mar 2021'	(b) (4), (b) (6)	15 Mar 2021 18:00:53

US3542168

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:18:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	15 Mar 2021 18:00:53

US3542168

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:18:34
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:00:53

US3542168

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:18:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Mar 2021 18:00:58

US3542168

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:50
User entered 'l'	System	15 Mar 2021 18:00:58

US3542168

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 18:27:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:09:22

US3542168

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:13

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System). User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 08:50:46
	David Diemert (b) (4)	01 Apr 2021 18:27:40
Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered with 'Conducted one day early due to participant availability. PD recorded.' (Site from System).	David Diemert (b) (4)	01 Apr 2021 18:27:03
User opened query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	01 Apr 2021 18:09:22
User entered '01 Apr 2021'	(b) (4), (b) (6)	01 Apr 2021 18:09:22

US3542168

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 18:27:40
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:09:22

US3542168

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:13

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	01 Apr 2021 18:09:22

US3542168

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:09:43

US3542168

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:09:43

US3542168

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:09:43

US3542168

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 18:09:43

US3542168

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:09:43

US3542168

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:09:43

US3542168

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:09:43

US3542168

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:09:43

US3542168

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 18:09:43

US3542168

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:09:43

US3542168

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 18:09:43

US3542168

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:09:43

US3542168

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 18:09:43

US3542168

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:09:43

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 18:09:43

US3542168

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:09:48

US3542168

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:13

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:09:48

US3542168

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:10:03

US3542168

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:12
User entered '01 Apr 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:10:03

US3542168

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:13

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	01 Apr 2021 21:43:12
User entered '10:35'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:10:03

US3542168

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
User entered '01 Apr 2021 10:35'	System	01 Apr 2021 18:10:03

US3542168

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:08:13

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:44:43
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:19:16
User signature succeeded.	David Diemert (b) (4)	18 Sep 2020 17:11:07
User entered 'Yes (Y)'	(b) (4) David Diemert (b) (4) (b) (4)	18 Sep 2020 17:10:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:52:51
User entered 'USA-US084-2020-mRNA-1273-P301000001'	System	20 Sep 2020 17:52:47
User entered 'New'	(b) (4), (b) (6)	20 Sep 2020 17:52:47

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:57:34
User closed query 'PV Query: Please consider keeping one event of anxiety exacerbation instead of two episodes, capture hospitalization dates from 10Sep to 23Sep, and event start date 10Sep and event end date 23Sep.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 16:14:03
Query 'PV Query: Please consider keeping one event of anxiety exacerbation instead of two episodes, capture hospitalization dates from 10Sep to 23Sep, and event start date 10Sep and event end date 23Sep.' answered with 'These are considered two discrete events from a clinical perspective' (Site from Safety).	Elissa Malkin (b) (4)	09 Nov 2020 21:06:57
User opened query 'PV Query: Please consider keeping one event of anxiety exacerbation instead of two episodes, capture hospitalization dates from 10Sep to 23Sep, and event start date 10Sep and event end date 23Sep.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 01:50:46
User signature succeeded.	David Diemert (b) (4)	31 Oct 2020 18:33:49
User closed query 'Per DM CLR: Please confirm if this AE is a worsening of the same condition noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 08:43:46
User closed query 'PV Query: Please consider updating the event term to "worsening of anxiety" if it matches the investigator's diagnosis and consider keeping one event instead of two episodes with capturing hospitalization dates from 10Sep to 23Sep.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 18:05:48
Query 'Per DM CLR: Please confirm if this AE is a worsening of the same condition noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria.' answered with 'Updated.' (Site from DM).	David Diemert (b) (4)	27 Oct 2020 20:20:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

[Adverse event](#)

Audit	User	Time (GMT)
Query 'PV Query: Please consider updating the event term to "worsening of anxiety" if it matches the investigator's diagnosis and consider keeping one event instead of two episodes with capturing hospitalization dates from 10Sep to 23Sep.' answered with 'Clarified.' (Site from Safety).	David Diemert (b) (4)	27 Oct 2020 20:20:01
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Exacerbation of anxiety - version MedDRA\23.0.	Coder Import (b) (4)	27 Oct 2020 20:19:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Oct 2020 20:19:28
Data point term sent to Coder	System	27 Oct 2020 20:18:45
DataPoint Un-verified.	David Diemert (b) (4)	27 Oct 2020 20:18:43
Coding entries removed.	David Diemert (b) (4)	27 Oct 2020 20:18:43
Signature has been broken.	David Diemert (b) (4)	27 Oct 2020 20:18:43
User entered 'ANXIETY Exacerbation' reason for change: Per Query Resolution	David Diemert (b) (4)	27 Oct 2020 20:18:43
User opened query 'Per DM CLR: Please confirm if this AE is a worsening of the same condition noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 09:29:17
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User opened query 'PV Query: Please consider updating the event term to "worsening of anxiety" if it matches the investigator's diagnosis and consider keeping one event instead of two episodes with capturing hospitalization dates from 10Sep to 23Sep.' (Site from Safety).	(b) (4), (b) (6)	06 Oct 2020 12:07:25
Query 'PV Query: Please consider updating the event term to "worsening of anxiety" if it matches the investigator's diagnosis.' canceled (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 22:03:59

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please consider updating the event term to "worsening of anxiety" if it matches the investigator's diagnosis.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 18:39:41
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 17:46:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 17:46:41
Data point term sent to Coder	System	18 Sep 2020 17:45:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:19
User entered 'Anxiety'	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	18 Sep 2020 17:45:19
User entered 'Yes (Y)'	(b) (4) David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	18 Sep 2020 17:45:19
User entered 'No (N)'	(b) (4) David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	18 Sep 2020 17:45:19
User entered 'No (N)'	(b) (4) David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	18 Sep 2020 17:45:19
User entered '10 Sep 2020'	(b) (4) David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	18 Sep 2020 17:45:19
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	18 Sep 2020 17:45:19
User entered 'No (N)'	(b) (4) David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	18 Sep 2020 17:45:19
User entered '18 Sep 2020'	(b) (4) David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	18 Sep 2020 17:45:19
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	18 Sep 2020 17:45:19
User entered 'Grade 4 (Grade 4)'	(b) (4) David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	18 Sep 2020 17:45:19
User entered 'Yes (Y)'	(b) (4) David Diemert (b) (4)	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	18 Sep 2020 17:45:19
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	18 Sep 2020 17:45:19
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	18 Sep 2020 17:45:19
User entered 'l'	(b) (4) David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	18 Sep 2020 17:45:19
User entered '10 Sep 2020'	(b) (4) David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	18 Sep 2020 17:45:19
User entered '18 Sep 2020'	(b) (4) David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	18 Sep 2020 17:45:19
User entered 'No (N)'	(b) (4) David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	18 Sep 2020 17:45:19
User entered empty.	(b) (4) David Diemert (b) (4)	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	18 Sep 2020 17:45:19
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	18 Sep 2020 17:45:19
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	18 Sep 2020 17:45:19
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	18 Sep 2020 17:45:19
User entered 'Not Related (NOT RELATED)'	(b) (4) David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	18 Sep 2020 17:45:19
User entered 'Not Related (NOT RELATED)'	(b) (4) David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	18 Sep 2020 17:45:19
User entered 'None (NONE)'	(b) (4) David Diemert (b) (4)	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	18 Sep 2020 17:45:19
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	18 Sep 2020 17:45:19
User entered 'l'	(b) (4) David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	18 Sep 2020 17:45:19
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	18 Sep 2020 17:45:19
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) David Diemert (b) (4)	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	18 Sep 2020 17:45:19
User entered empty.	(b) (4) David Diemert (b) (4)	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is received.' canceled (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 15:43:09
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 01:51:42
User closed query 'PV Query: Please provide the start date for the concomitant medication, hydroxyurea.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 18:05:56
Query 'PV Query: Please provide the start date for the concomitant medication, hydroxyurea.' answered with 'This was corrected on the Con Med log.' (Site from Safety).	David Diemert (b) (4) (b) (4)	27 Oct 2020 20:22:20
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User opened query 'PV Query: Please provide the start date for the concomitant medication, hydroxyurea.' (Site from Safety).	(b) (4), (b) (6)	06 Oct 2020 12:08:31
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). As mentioned, please add Remeron as a concomitant medication.' canceled (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 22:04:52
Query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. As mentioned, anxiety and depression should be captured as medical histories.' canceled (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 22:04:49
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 22:04:44

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). As mentioned, please add Remeron as a concomitant medication.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 18:39:15
User opened query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. As mentioned, anxiety and depression should be captured as medical histories.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 18:39:02
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 18:38:50
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:19

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Participant reported to site on 18SEP2020 that he had just been discharged from hospital this day after having been admitted to the psychiatric service on 10SEP2020 due to worsened anxiety. He states that he has pre-existing diagnoses of anxiety and depression for the past 20 years that were not related to the study team at screening/enrollment. He has been treated for the past year with Remeron 15mg/day (also not reported to the study team at screening/enrollment). According to the participant, his girlfriend was recently diagnosed with cervical cancer, which led to worsened symptoms of anxiety on 10SEP2020, prompting him to go to the Emergency Department of a local community hospital (not at the study site). He was admitted to the Psychiatry service for medication adjustment. His dose of Remeron was increased to 30mg/day according to the participant. During his in-patient stay his symptoms of anxiety improved and he was therefore discharged home the morning of 18SEP2020. He will follow-up with his regular psychiatrist. He denies having any potential COVID-19 symptoms: no fever, chills, dyspnea, cough, loss of taste or smell, rhinorrhea, nasal congestion, sore throat, myalgias, arthralgias, headache, fatigue, nausea, or diarrhea. No recent travel or sick contacts. He received his first dose of vaccine/placebo on 04SEPT2020.'	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Sep 2020 17:45:07

US3542168

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:13

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:31:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:00:42
User entered 'USA-US084-2020-mRNA-1273-P301000001'	(b) (4), (b) (6)	28 Sep 2020 14:00:30

US3542168

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:13

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:57:27
User signature succeeded.	David Diemert (b) (4)	31 Oct 2020 18:33:49
User closed query 'Per DM CLR: Review if this AE is related to the previously recorded AE #2 (10 SEP 2020). Note that downgrades in intensity are not recorded as separate AEs. The highest grade of the AE remains ongoing until event resolves. Review and update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 08:43:58
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Exacerbation of anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 20:25:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 20:25:40
Data point term sent to Coder	System	27 Oct 2020 20:24:55
Query 'Per DM CLR: Review if this AE is related to the previously recorded AE #2 (10 SEP 2020). Note that downgrades in intensity are not recorded as separate AEs. The highest grade of the AE remains ongoing until event resolves. Review and update eCRF as appropriate. ' answered with 'This individual had two separate episodes of anxiety exacerbation, with resolution in between them.' (Site from DM).	David Diemert (b) (4)	27 Oct 2020 20:24:02
DataPoint Un-verified.	David Diemert (b) (4)	27 Oct 2020 20:23:56
Coding entries removed.	David Diemert (b) (4)	27 Oct 2020 20:23:56
Signature has been broken.	David Diemert (b) (4)	27 Oct 2020 20:23:56
User entered 'ANXIETY Exacerbation' reason for change: New Information	David Diemert (b) (4)	27 Oct 2020 20:23:56
User opened query 'Per DM CLR: Review if this AE is related to the previously recorded AE #2 (10 SEP 2020). Note that downgrades in intensity are not recorded as separate AEs. The highest grade of the AE remains ongoing until event resolves. Review and update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 09:29:40

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:13

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety disorders NEC, PT: Anxiety disorder, LLT: Anxiety disorder - version MedDRA\\23.0.	Coder Import (b) (4)	26 Sep 2020 22:26:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Sep 2020 22:26:53
User signature succeeded.	David Diemert (b) (4)	26 Sep 2020 22:26:17
Data point term sent to Coder	(b) (4) System	26 Sep 2020 22:26:08
User entered 'Anxiety Disorder'	David Diemert (b) (4)	26 Sep 2020 22:25:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	26 Sep 2020 22:26:17
User entered 'Yes (Y)'	(b) (4) David Diemert (b) (4)	26 Sep 2020 22:25:44

US3542168

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	26 Sep 2020 22:26:17
User entered 'No (N)'	(b) (4) David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

US3542168

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User closed query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' (Site from Safety). Query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' answered with 'Field updated to no' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 12:37:20
Signature has been broken.	Hannah Yellin (b) (4)	29 Sep 2020 20:59:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	29 Sep 2020 20:59:31
User opened query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' (Site from Safety). User signature succeeded.	Hannah Yellin (b) (4)	29 Sep 2020 20:59:31
	(b) (4)	29 Sep 2020 13:51:38
	(b) (4), (b) (6)	29 Sep 2020 13:51:38
	David Diemert (b) (4)	26 Sep 2020 22:26:17
User entered 'Yes (Y)'	(b) (4)	26 Sep 2020 22:25:44
	David Diemert (b) (4)	26 Sep 2020 22:25:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	26 Sep 2020 22:26:17
User entered '19 Sep 2020'	(b) (4) David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

US3542168

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:13

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	26 Sep 2020 22:26:17
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

US3542168

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 22:25:44

US3542168

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:13

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	26 Sep 2020 22:26:17
User entered 'No (N)'	(b) (4) David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

US3542168

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	26 Sep 2020 22:26:17
User entered '23 Sep 2020'	(b) (4) David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:13

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	26 Sep 2020 22:26:17
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 22:25:44

US3542168

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:13

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	26 Sep 2020 22:26:17
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) David Diemert (b) (4)	26 Sep 2020 22:25:44

US3542168

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	26 Sep 2020 22:26:17
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4) System	26 Sep 2020 22:26:06
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	26 Sep 2020 22:25:44
User entered 'Yes (Y)'	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

US3542168

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:13

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	26 Sep 2020 22:26:17
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

US3542168

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:13

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	26 Sep 2020 22:26:17
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

US3542168

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	26 Sep 2020 22:26:17
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	26 Sep 2020 22:26:06
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	26 Sep 2020 22:26:06
User entered '1' reason for change: Data Entry Error	David Diemert (b) (4)	26 Sep 2020 22:26:06
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	26 Sep 2020 22:25:44
User entered '0'	System	26 Sep 2020 22:25:44
	David Diemert (b) (4)	26 Sep 2020 22:25:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	26 Sep 2020 22:26:17
User entered '19 Sep 2020'	(b) (4) David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:13

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	26 Sep 2020 22:26:17
User entered '23 Sep 2020'	(b) (4) David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	26 Sep 2020 22:26:17
User entered 'No (N)'	(b) (4) David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	26 Sep 2020 22:26:17
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	26 Sep 2020 22:26:17
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	26 Sep 2020 22:26:17
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	26 Sep 2020 22:26:17
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	26 Sep 2020 22:26:17
User entered 'Not Related (NOT RELATED)'	(b) (4) David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	26 Sep 2020 22:26:17
User entered 'Not Related (NOT RELATED)'	(b) (4) David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:13

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Per DM CLR-RQ: Site's response noted. However, Primary Reason for Dosing Discontinuation is not recorded as AE. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	05 Feb 2021 04:30:46
Query 'Per DM CLR-RQ: Site's response noted. However, Primary Reason for Dosing Discontinuation is not recorded as AE. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' answered with 'The unrelated AE in and of itself was not the reason for discontinuation of dosing; rather, it was that the participant is unstable from a psychiatric perspective and the PI did not want to confuse safety assessment of the vaccine.' (Site from DM).	David Diemert (b) (4)	04 Feb 2021 22:37:18
User opened query 'Per DM CLR-RQ: Site's response noted. However, Primary Reason for Dosing Discontinuation is not recorded as AE. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM). DataPoint Verified.	David Diemert (b) (4)	02 Feb 2021 22:23:33
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	19 Jan 2021 13:08:08
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'Primary reason for Dosing Discontinuation, as recorded on the Exposure eCRF for Visit 2, HAS been listed as due to AE. Please verify.' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 15:22:03
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 08:32:48
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'Primary reason for Dosing Discontinuation, as recorded on the Exposure eCRF for Visit 2, HAS been listed as due to AE. Please verify.' (Site from System).	David Diemert (b) (4)	21 Nov 2020 22:17:50
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	21 Nov 2020 22:15:12

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	David Diemert (b) (4)	21 Nov 2020 22:15:12
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	21 Nov 2020 22:15:12
	(b) (4)	
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: New Information	David Diemert (b) (4)	21 Nov 2020 22:15:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	26 Sep 2020 22:26:17
	(b) (4)	
User entered 'None (NONE)'	David Diemert (b) (4)	26 Sep 2020 22:25:44
	(b) (4)	

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Folder: Adverse Events

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None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	26 Sep 2020 22:26:17
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	26 Sep 2020 22:26:17
User entered 'l'	(b) (4) David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	26 Sep 2020 22:26:17
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:13

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	26 Sep 2020 22:26:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:13

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	26 Sep 2020 22:26:17
User entered empty.	(b) (4) David Diemert (b) (4)	26 Sep 2020 22:25:44

US3542168

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:13

[Narrative](#)

Audit	User	Time (GMT)
Query 'Please verify if patient diagnosed with Borderline Personality Disorder in hospital. Per medical history start date is UN/UNK/2000.' canceled (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 17:12:52
User opened query 'Please verify if patient diagnosed with Borderline Personality Disorder in hospital. Per medical history start date is UN/UNK/2000.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 17:12:34
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 18:06:06
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Not currently available.' (Site from Safety). DataPoint Verified.	David Diemert (b) (4) (b) (4)	27 Oct 2020 20:24:27
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	15 Oct 2020 15:20:24 06 Oct 2020 12:06:30
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:26:17
User entered 'Participant called study team on 24SEP2020 to report that he had been re-admitted to the psychiatric ward of a local hospital on 19SEP2020 due to recurrence of symptoms of severe anxiety. While in hospital he was diagnosed with borderline personality disorder and started on both lithium and mirtazipine, with improvement of symptoms. He was discharged on 23SEP2020 with follow-up planned with outpatient psychiatry.'	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

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Folder: Adverse Events

Form: Adverse Events (2)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Sep 2020 22:25:44

US3542168

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Sep 2020 22:25:44

US3542168

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Sep 2020 22:25:44

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Folder: Adverse Events

Form: Adverse Events (3)

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[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 17:32:35
User entered 'USA-US084-2020-mRNA-1273-P301000001'	(b) (4), (b) (6)	30 Sep 2020 17:32:26

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression aggravated - version MedDRA\23.0.	Coder Import (b) (4)	30 Sep 2020 15:18:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	30 Sep 2020 15:18:56
Data point term sent to Coder	System	30 Sep 2020 14:55:02
User entered 'depression exacerbation'	Taylor Ladson (b) (4)	30 Sep 2020 14:54:24

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Folder: Adverse Events

Form: Adverse Events (3)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:54:24

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Folder: Adverse Events

Form: Adverse Events (3)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:54:24

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:54:24

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Folder: Adverse Events

Form: Adverse Events (3)

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '19 Sep 2020'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:54:24

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:13

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:54:24

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 14:54:24

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:13

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:54:24

US3542168

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '23 Sep 2020'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:54:24

US3542168

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:13

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:54:24

US3542168

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 14:54:24

US3542168

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:13

[Severity](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please consider updating severity of event of depression to grade 4.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 17:27:30
Query 'PV Query: Please consider updating severity of event of depression to grade 4.' answered with 'Depression was not Grade 4. It was not the primary reason for the admission.' (Site from Safety).	David Diemert (b) (4) (b) (4)	12 Nov 2020 22:11:26
User opened query 'PV Query: Please consider updating severity of event of depression to grade 4.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 01:49:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'Grade 3/Severe (Grade 3/Severe)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:54:24

US3542168

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:54:24

US3542168

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:13

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '0'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:54:24

US3542168

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:13

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '0'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:54:24

US3542168

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'l'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:54:24

US3542168

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '19 Sep 2020'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:54:24

US3542168

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:13

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '23 Sep 2020'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:54:24

US3542168

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:54:24

US3542168

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:54:24

US3542168

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '0'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:54:24

US3542168

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '0'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:54:24

US3542168

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:13

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '0'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:54:24

US3542168

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'Not Related (NOT RELATED)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:54:24

US3542168

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'Not Related (NOT RELATED)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:54:24

US3542168

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:13

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'None (NONE)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:54:24

US3542168

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:13

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '0'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:54:24

US3542168

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'l'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:54:24

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '0'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:54:24

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:13

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:54:24

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:13

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:54:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:13

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	(b) (4) System	30 Sep 2020 15:04:41
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	30 Sep 2020 15:04:41
User entered 'Participant went to emergency department to be treated for lower leg pain, thought to be attributed to sickle cell disease. He was then admitted to the psych department for exacerbation of chronic anxiety and depression. He was diagnosed with PTSD and borderline personality disorder and given medication for treatment.' reason for change: Data Entry Error	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 15:04:41
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	30 Sep 2020 14:54:24
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:54:24

US3542168

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:13

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	30 Sep 2020 14:54:24

US3542168

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Sep 2020 14:54:24

US3542168

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Sep 2020 14:54:24

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Pain in extremity, LLT: Leg pain - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:32:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:32:52
Data point term sent to Coder	System	30 Sep 2020 14:56:04
User entered 'lower leg pain'	Taylor Ladson (b) (4)	30 Sep 2020 14:55:14

US3542168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

US3542168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

US3542168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

US3542168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '18 Sep 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

US3542168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49
User entered empty.	System	30 Sep 2020 14:55:14

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

US3542168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '19 Sep 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

US3542168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

US3542168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49
User entered empty.	System	30 Sep 2020 14:55:14

US3542168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

US3542168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

US3542168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

US3542168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

US3542168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

US3542168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

US3542168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

US3542168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

US3542168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

US3542168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'Not Related (NOT RELATED)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

US3542168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'Not Related (NOT RELATED)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

US3542168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'None (NONE)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

US3542168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

US3542168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'l'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

US3542168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

US3542168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

US3542168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

US3542168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

US3542168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49
User entered '0'	System	30 Sep 2020 14:55:14

US3542168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49
User entered 'I'	System	30 Sep 2020 14:55:14

US3542168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:14:49

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54
DataPoint Un-verified.	(b) (4), (b) (6)	17 Feb 2021 19:22:16
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:22:14
User closed query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 05:35:31
Query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' answered with 'Symptom duration was for less than 48 hrs and therefore an Illness Visit was not required per protocol.' (Site from DM).	David Diemert (b) (4)	03 Jan 2021 00:51:20
User opened query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 05:46:03
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Rhinorrhoea, LLT: Rhinorrhea - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 11:33:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 11:33:11
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
Data point term sent to Coder	System (b) (4)	02 Nov 2020 19:56:29
User entered 'Rhinorrhea'	Erika Faust (b) (4)	02 Nov 2020 19:56:04

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered '21 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54
User entered empty.	System	02 Nov 2020 19:56:04

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered '23 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54
User entered empty.	System	02 Nov 2020 19:56:04

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered empty.	(b) (4) Erika Faust (b) (4)	02 Nov 2020 19:56:04

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered 'Not Related (NOT RELATED)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered 'Not Related (NOT RELATED)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered 'None (NONE)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered 'l'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Erika Faust (b) (4)	02 Nov 2020 19:56:04

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

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 21:42:54
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54
User entered '0'	System	02 Nov 2020 19:56:04

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54
User entered '0'	System	02 Nov 2020 19:56:04

US3542168

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:54

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59
User closed query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 05:35:45
Query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' answered with 'Symptom duration was less than 48 hours and therefore an Illness Visit was not required as per protocol.' (Site from DM).	David Diemert (b) (4) (b) (4)	03 Jan 2021 00:51:57
User opened query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 05:47:13
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 11:37:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 11:37:03
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
Data point term sent to Coder	System	02 Nov 2020 19:57:29
User entered 'Headache'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered '21 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59
User entered empty.	System	02 Nov 2020 19:56:53

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered '23 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59
User entered empty.	System	02 Nov 2020 19:56:53

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered 'Not Related (NOT RELATED)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered 'Not Related (NOT RELATED)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered 'None (NONE)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered 'l'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Erika Faust (b) (4)	02 Nov 2020 19:56:53

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

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 21:42:59
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:24:13
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59
User entered '0'	System	02 Nov 2020 19:56:53

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59
User entered '0'	System	02 Nov 2020 19:56:53

US3542168

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:42:59

US3542168

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02

US3542168

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:37:18
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Muscle strain, LLT: Muscle strain - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 23:21:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 23:21:41
Data point term sent to Coder	System	13 Nov 2020 17:32:02
User entered 'Right trapezius strain'	Erika Faust (b) (4)	13 Nov 2020 17:31:19

US3542168

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:37:18
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

US3542168

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:37:18
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

US3542168

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:37:18
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

US3542168

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:37:18
User entered '10 Nov 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

US3542168

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:37:18
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

US3542168

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02
User entered empty.	System	13 Nov 2020 17:31:19

US3542168

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:37:18
User entered 'No (N)' reason for change: New Information	(b) (4) Taylor Ladson (b) (4)	12 Jan 2021 20:54:10
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	13 Nov 2020 17:31:19

US3542168

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:37:18
User entered '22 Dec 2020' reason for change: New Information	(b) (4)	
	Taylor Ladson (b) (4)	12 Jan 2021 20:54:10
User entered empty.	(b) (4)	
	Erika Faust (b) (4)	13 Nov 2020 17:31:19
	(b) (4)	

US3542168

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:37:18
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

US3542168

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02
User entered empty.	System	13 Nov 2020 17:31:19

US3542168

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:37:18
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

US3542168

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:37:18
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 17:31:28
User entered 'No (N)' reason for change: Data Entry Error	Erika Faust (b) (4)	13 Nov 2020 17:31:28
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	13 Nov 2020 17:31:19
	Erika Faust (b) (4)	13 Nov 2020 17:31:19
	(b) (4)	

US3542168

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:37:18
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

US3542168

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:37:18
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

US3542168

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:37:18
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

US3542168

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:37:18
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

US3542168

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:37:18
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

US3542168

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:37:18
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:37:18
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

US3542168

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:37:18
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

US3542168

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:37:18
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

US3542168

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:37:18
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

US3542168

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:37:18
User entered 'Not Related (NOT RELATED)'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

US3542168

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:37:18
User entered 'Not Related (NOT RELATED)'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

US3542168

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:37:18
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Erika Faust (b) (4)	13 Nov 2020 17:31:19

US3542168

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:37:18
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

US3542168

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:37:18
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 05:46:55
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'Con med indication updated to match verbatim.' (Site from DM).	David Diemert (b) (4)	02 Feb 2021 22:24:49
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	26 Dec 2020 21:11:37
User entered 'I'	Erika Faust (b) (4)	13 Nov 2020 17:31:19

US3542168

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:37:18
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

US3542168

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:37:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
New Information	Taylor Ladson (b) (4)	12 Jan 2021 20:54:10
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4)	
	Erika Faust (b) (4)	13 Nov 2020 17:31:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

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 21:43:02
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:37:18
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

US3542168

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:37:18
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

US3542168

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02
User entered '0'	System	13 Nov 2020 17:31:28

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02
User entered '0'	System	13 Nov 2020 17:31:19

US3542168

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:43:02

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:44:43
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:09
User closed query 'Per ETRTR: Please confirm Medication, dates and dosing of ConMeds provided at hospitalization for SAE Anxiety, thanks.' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 21:07:29
Query 'Per ETRTR: Please confirm Medication, dates and dosing of ConMeds provided at hospitalization for SAE Anxiety, thanks.' answered with 'This was already done. Why is this being queried?' (Site from CRA).	David Diemert (b) (4) (b) (4)	27 Oct 2020 20:25:58
User opened query 'Per ETRTR: Please confirm Medication, dates and dosing of ConMeds provided at hospitalization for SAE Anxiety, thanks.' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 20:53:42
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:48:41

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:13

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
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.	Coder Import (b) (4)	21 Sep 2020 18:50:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 18:50:55
Data point term sent to Coder	System	21 Sep 2020 18:49:35
User entered 'lisinopril'	Taylor Ladson (b) (4)	21 Sep 2020 18:49:08

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:13

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Sep 2020 18:49:08

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:13

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'hypertension'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:49:08

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:13

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '20'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:49:08

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:13

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'mg (mg)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:49:08

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:13

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Sep 2020 18:49:08

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:13

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'once daily (QD)'	(b) (4) Taylor Ladson (b) (4)	21 Sep 2020 18:49:08

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:49:08

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:13

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4)	21 Sep 2020 18:49:08

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:13

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:49:08

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'un UNK 2018'	(b) (4) Taylor Ladson (b) (4)	21 Sep 2020 18:49:08

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:49:08

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:13

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Sep 2020 18:49:08

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Sep 2020 18:49:08

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Sep 2020 18:49:08

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	21 Sep 2020 18:49:08

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Sep 2020 18:49:08

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 18:49:08

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:28:21
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: MIRTAZAPINE, PRODUCTSYNONYM: REMERON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 18:51:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 18:51:51
Data point term sent to Coder	System	21 Sep 2020 18:50:36
User entered 'remeron'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:01

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:28:21
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:01

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:28:21
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'generalized anxiety disorder'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:01

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:28:21
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '15'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:01

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:28:21
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'mg (mg)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:01

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:28:21
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:01

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:28:21
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'once daily (QD)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:01

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:28:21
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:01

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:28:21
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:01

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:28:21
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:01

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:28:21
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'un UNK 2019'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:01

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:28:21
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:01

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:28:21
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:01

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:28:21
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '10 Sep 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:01

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:28:21
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:01

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:28:21
User entered 'I'	System	21 Sep 2020 18:50:01

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:28:21
User entered 'I'	System	21 Sep 2020 18:50:01

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:28:21
User entered '804 (804)'	System	21 Sep 2020 18:50:01

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:13

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: MIRTAZAPINE, PRODUCTSYNONYM: REMERON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 13:18:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 13:18:34
Data point term sent to Coder	System	24 Mar 2021 13:18:00
Coding entries removed.	David Diemert (b) (4)	24 Mar 2021 13:17:37
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: MIRTAZAPINE, PRODUCTSYNONYM: REMERON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 18:51:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 18:51:51
Data point term sent to Coder	System	21 Sep 2020 18:50:36
User entered 'remeron'	Taylor Ladson (b) (4)	21 Sep 2020 18:50:22

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:13

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:22

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:13

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 13:48:49
User signature succeeded.	David Diemert (b) (4)	24 Mar 2021 16:47:23
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	24 Mar 2021 13:17:37
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	24 Mar 2021 13:17:37
User entered 'GENERALIZED ANXIETY DISORDER exacerbation' reason for change: New Information	David Diemert (b) (4)	24 Mar 2021 13:17:37
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'generalized anxiety disorder'	(b) (4)	
	Taylor Ladson (b) (4)	21 Sep 2020 18:50:22
	(b) (4)	

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:13

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '30'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:22

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:13

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'mg (mg)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:22

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:13

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:22

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:13

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'once daily (QD)'	(b) (4) Taylor Ladson (b) (4)	21 Sep 2020 18:50:22

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:22

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:13

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4)	21 Sep 2020 18:50:22

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:13

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:22

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '10 Sep 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:22

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:22

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:13

[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)	07 Apr 2021 06:56:45
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 'The participant will continue on this med and dose indefinitely to prevent another crisis and hospitalization. You don't stop a med that has resulted in someone's depression to be controlled. That would be malpractice.' (Site from DM).	David Diemert (b) (4)	06 Apr 2021 13:32:22
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)	06 Apr 2021 11:26:02
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'Yes (Y)'	Taylor Ladson (b) (4)	21 Sep 2020 18:50:22

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:22

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:22

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	21 Sep 2020 18:50:22

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Sep 2020 18:50:22

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 18:50:22

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:13

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: MIRTAPAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 11:55:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 11:55:51
Data point term sent to Coder Coding entries removed.	System	10 Mar 2021 17:42:47
	David Diemert (b) (4)	10 Mar 2021 17:42:45
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: MIRTAPAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 14:46:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 14:46:48
Data point term sent to Coder	System	30 Sep 2020 14:45:47
User entered 'mirtapazine'	Taylor Ladson (b) (4)	30 Sep 2020 14:45:28

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:13

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:45:28

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:13

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 13:48:54
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:45:16
User closed query 'Per DM CLR: Please review indication and confirm if this Con Med was given for AE #3. If yes, please update indication to reflect a match with this Con Med indication as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 07:43:22
Query 'Per DM CLR: Please review indication and confirm if this Con Med was given for AE #3. If yes, please update indication to reflect a match with this Con Med indication as appropriate.' answered with 'Updated.' (Site from DM).	David Diemert (b) (4)	10 Mar 2021 17:42:55
DataPoint Un-verified.	David Diemert (b) (4)	10 Mar 2021 17:42:45
Signature has been broken.	David Diemert (b) (4)	10 Mar 2021 17:42:45
User entered 'DEPRESSION exacerbation' reason for change: Per Query Resolution	David Diemert (b) (4)	10 Mar 2021 17:42:45
User opened query 'Per DM CLR: Please review indication and confirm if this Con Med was given for AE #3. If yes, please update indication to reflect a match with this Con Med indication as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 10:40:03
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'depression'	Taylor Ladson (b) (4)	30 Sep 2020 14:45:28

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:13

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:21:18
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage (eg, 15 mg, 30 mg, 45 mg) or provide explanation for alternate dosage.	(b) (4), (b) (6)	15 Feb 2021 08:31:51
' (Site from DM).		
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage (eg, 15 mg, 30 mg, 45 mg) or provide explanation for alternate dosage.	David Diemert (b) (4)	13 Feb 2021 20:11:18
' answered with 'Corrected	(b) (4)	
' (Site from DM).		
DataPoint Un-verified.	David Diemert (b) (4)	13 Feb 2021 20:10:10
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	13 Feb 2021 20:10:10
User entered '30' reason for change: New Information	(b) (4)	
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage (eg, 15 mg, 30 mg, 45 mg) or provide explanation for alternate dosage.	David Diemert (b) (4)	13 Feb 2021 20:10:10
' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 21:15:47
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '3'	(b) (4)	
	Taylor Ladson (b) (4)	30 Sep 2020 14:45:28
	(b) (4)	

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:13

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'mg (mg)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:45:28

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:13

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:45:28

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:13

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'once daily (QD)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:45:28

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:45:28

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:13

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:45:28

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:13

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:45:28

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '20 Sep 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:45:28

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:45:28

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:13

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 08:02:35
Query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' answered with 'The exacerbation depression resolved because of the medication. The medication has to be continued as maintenance treatment indefinitely.' (Site from DM).	David Diemert (b) (4) (b) (4)	24 Mar 2021 13:19:31
User opened query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 06:59:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:45:28

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:45:28

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:45:28

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	30 Sep 2020 14:45:28

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Sep 2020 14:45:28

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 14:45:28

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:13

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: LITHIUM, PRODUCT: LITHIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 13:32:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 13:32:26
Data point term sent to Coder	System	24 Mar 2021 13:20:01
Coding entries removed.	David Diemert (b) (4)	24 Mar 2021 13:20:01
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: LITHIUM, PRODUCT: LITHIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 15:32:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 15:32:52
Data point term sent to Coder	System	30 Sep 2020 14:47:53
User entered 'lithium'	Taylor Ladson (b) (4)	30 Sep 2020 14:47:21

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:13

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:47:21

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:13

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 13:49:08
User signature succeeded.	David Diemert (b) (4)	24 Mar 2021 16:47:23
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	24 Mar 2021 13:20:01
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	24 Mar 2021 13:20:01
User entered 'DEPRESSION AND ANXIETY exacerbation' reason for change: Per Query Resolution	David Diemert (b) (4)	24 Mar 2021 13:20:01
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'depression and anxiety'	(b) (4)	
	Taylor Ladson (b) (4)	30 Sep 2020 14:47:21
	(b) (4)	

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:13

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '300'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:47:21

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:13

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'mg (mg)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:21

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:13

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:47:21

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:13

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'once daily (QD)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:47:21

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:21

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:13

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:47:21

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:13

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:21

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '20 Sep 2020'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:47:21

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:21

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:13

[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)	07 Apr 2021 06:57:17
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 'Stopping lithium would likely result in a mental health crisis. He's controlled with this medication so it will be continued indefinitely.' (Site from DM).	David Diemert (b) (4)	06 Apr 2021 13:34:03
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)	06 Apr 2021 11:26:11
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'Yes (Y)'	Taylor Ladson (b) (4)	30 Sep 2020 14:47:21

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:21

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:47:21

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	30 Sep 2020 14:47:21

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Sep 2020 14:47:21

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 14:47:21

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:13

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ANTIADRENERGIC AGENTS, PERIPHERALLY ACTING, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: PRAZOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 14:48:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 14:48:54
Data point term sent to Coder	System	30 Sep 2020 14:47:53
User entered 'prazosin'	Taylor Ladson (b) (4)	30 Sep 2020 14:47:50

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:13

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:47:50

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:13

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'PTSD'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:47:50

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:13

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '3'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:50

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:13

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'mg (mg)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:47:50

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:13

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:47:50

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:13

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'once daily (QD)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:47:50

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:50

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:13

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:47:50

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:13

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:50

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '20 Sep 2020'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:47:50

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:50

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:13

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:47:50

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:50

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:47:50

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	30 Sep 2020 14:47:50

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Sep 2020 14:47:50

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 14:47:50

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:13

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User closed query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening).' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 17:45:31
Query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening).' answered with 'Confirmed this medication does not meet exclusion criterion #12' (Site from DM).	Elissa Malkin (b) (4)	20 Oct 2020 15:03:00
User opened query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening).' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 14:55:08
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: OTHER HEMATOLOGICAL AGENTS, ATC: OTHER HEMATOLOGICAL AGENTS, PRODUCT: HYDROXYCARBAMIDE, PRODUCTSYNONYM: HYDROXYUREA - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Sep 2020 15:22:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Sep 2020 15:22:53
Data point term sent to Coder	System	30 Sep 2020 14:48:54
User entered 'HYDROXYUREA'	Taylor Ladson (b) (4)	30 Sep 2020 14:48:29

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:13

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:48:29

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:13

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'SICKLE CELL DISEASE'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:48:29

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:13

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '500'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:48:29

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:13

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'mg (mg)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:48:29

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:13

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:48:29

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:13

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'once daily (QD)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:48:29

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:48:29

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:13

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:48:29

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:13

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:48:29

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	27 Oct 2020 20:21:50
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	27 Oct 2020 20:21:38
	(b) (4)	
User entered 'UN May 2020' reason for change:	David Diemert (b) (4)	27 Oct 2020 20:21:38
Data Entry Error	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
	(b) (4)	
User entered empty.	Taylor Ladson (b) (4)	30 Sep 2020 14:48:29
	(b) (4)	

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	27 Oct 2020 20:21:50
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	27 Oct 2020 20:21:38
	(b) (4)	
User entered '0' reason for change: Data Entry Error	David Diemert (b) (4)	27 Oct 2020 20:21:38
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
	(b) (4)	
User entered '1'	Taylor Ladson (b) (4)	30 Sep 2020 14:48:29
	(b) (4)	

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:13

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:48:29

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:48:29

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 14:48:29

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	30 Sep 2020 14:48:29

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Sep 2020 14:48:29

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 14:48:29

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:48
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Sep 2020 15:36:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:36:56
Data point term sent to Coder	System	30 Sep 2020 14:49:55
User entered 'morphine'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:03

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:48
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:03

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:48
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'lower leg pain'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:03

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:48
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '4'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:03

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:48
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'mg (mg)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:03

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:48
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:03

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:48
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'once (ONCE)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:03

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:48
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:03

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:48
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:03

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:48
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:03

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:48
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '19 Sep 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:03

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:48
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:03

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:48
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:03

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:48
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '19 Sep 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:03

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:48
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:03

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:48
User entered empty.	System	30 Sep 2020 14:49:03

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:48
User entered empty.	System	30 Sep 2020 14:49:03

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:48
User entered empty.	System	30 Sep 2020 14:49:03

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:08
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 14:50:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 14:50:49
Data point term sent to Coder	System	30 Sep 2020 14:49:55
User entered 'dilaudid'	Taylor Ladson (b) (4)	30 Sep 2020 14:49:49

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:08
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:49

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:08
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'lower leg pain'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:49

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:08
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'l'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:49

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:08
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'mg (mg)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:49

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:08
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:49

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:08
User closed query 'Per subject source frequency is twice. Please verify and update if needed. ' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 15:20:51
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:44
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
Query 'Per subject source frequency is twice. Please verify and update if needed. ' answered with 'updated' (Site from CRA).	Elissa Malkin (b) (4)	17 Nov 2020 20:51:34
Signature has been broken.	Elissa Malkin (b) (4)	17 Nov 2020 20:51:25
User entered 'other (OTHER)' reason for change:	Elissa Malkin (b) (4)	17 Nov 2020 20:51:25
Per Query Resolution	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:10
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User opened query 'Per subject source frequency is twice. Please verify and update if needed. ' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 17:04:19
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'once (ONCE)'	Taylor Ladson (b) (4)	30 Sep 2020 14:49:49

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:08
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:46
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Un-verified.	(b) (4)	
	Elissa Malkin (b) (4)	17 Nov 2020 20:51:25
Signature has been broken.	(b) (4)	
	Elissa Malkin (b) (4)	17 Nov 2020 20:51:25
User entered 'twice' reason for change: Per Query Resolution	(b) (4)	
	Elissa Malkin (b) (4)	17 Nov 2020 20:51:25
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4)	
	Taylor Ladson (b) (4)	30 Sep 2020 14:49:49
	(b) (4)	

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:08
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:49

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:08
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:49

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:08
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '19 Sep 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:49

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:08
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:49

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:08
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:49

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:08
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '19 Sep 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:49

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:08
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:49

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:08
User entered empty.	System	30 Sep 2020 14:49:49

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:08
User entered empty.	System	30 Sep 2020 14:49:49

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:17:08
User entered empty.	System	30 Sep 2020 14:49:49

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:09:36
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 20:54:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 20:54:42
Data point term sent to Coder	System	11 Jan 2021 19:37:03
Coding entries removed.	Erika Faust (b) (4) (b) (4)	11 Jan 2021 19:36:55
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:17:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:17:53
Data point term sent to Coder	System	30 Sep 2020 14:50:57
User entered 'benadryl'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:50:23

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:09:36
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:50:23

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:09:36
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 13:49:25
Query 'Please confirm indication. Benadryl not normally used for pain relief. ' canceled (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 17:14:00
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User opened query 'Please confirm indication. Benadryl not normally used for pain relief. ' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 17:06:11
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'lower leg pain'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:50:23

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:09:36
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '25'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:50:23

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:09:36
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'mg (mg)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:50:23

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:09:36
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:50:23

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:09:36
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'once (ONCE)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:50:23

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:09:36
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:50:23

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:09:36
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 13:49:30
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
DataPoint Un-verified.	(b) (4)	
	Erika Faust (b) (4)	11 Jan 2021 19:36:55
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	11 Jan 2021 19:36:55
User entered 'Intravenous (INTRAVENOUS)'	(b) (4)	
reason for change: Data Entry Error	Erika Faust (b) (4)	11 Jan 2021 19:36:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
	(b) (4)	
User entered 'Oral (ORAL)'	Taylor Ladson (b) (4)	30 Sep 2020 14:50:23
	(b) (4)	

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:09:36
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:50:23

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:09:36
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '19 Sep 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:50:23

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:09:36
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:50:23

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:09:36
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:50:23

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:09:36
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '19 Sep 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:50:23

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:09:36
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:50:23

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:09:36
User entered empty.	System	30 Sep 2020 14:50:23

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:09:36
User entered empty.	System	30 Sep 2020 14:50:23

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 14:09:36
User entered empty.	System	30 Sep 2020 14:50:23

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:07:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:17:43
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 05:17:43
Data point term sent to Coder	System	13 Nov 2020 17:33:03
User entered 'Oxycodone'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:32:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:32:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'Sickle cell disease'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:32:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered '10'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:32:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'mg (mg)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:32:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered empty.	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:32:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'as needed (PRN)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:32:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered empty.	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:32:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'Oral (ORAL)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:32:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered empty.	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:32:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'UN Aug 2020'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:32:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered '0'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:32:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:32:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered empty.	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:32:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:32:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 17:32:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 17:32:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 17:32:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:13

[Name of Medication](#)

Audit	User	Time (GMT)
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, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 09:07:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 09:07:41
Data point term sent to Coder	System	02 Feb 2021 22:24:43
Coding entries removed.	David Diemert (b) (4) (b) (4)	02 Feb 2021 22:24:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
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, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 17:35:46
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 17:35:46
Data point term sent to Coder	System	13 Nov 2020 17:35:03
User entered 'Motrin'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:34:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:34:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:13

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 13:49:40
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:03:54
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 09:21:48
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'Updated.' (Site from DM).	David Diemert (b) (4)	02 Feb 2021 22:24:31
DataPoint Un-verified.	David Diemert (b) (4)	02 Feb 2021 22:24:26
Signature has been broken.	David Diemert (b) (4)	02 Feb 2021 22:24:26
User entered 'Right trapezius strain.' reason for change: Per Query Resolution	David Diemert (b) (4)	02 Feb 2021 22:24:26
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 14:29:39
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'Neck pain'	Erika Faust (b) (4)	13 Nov 2020 17:34:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered '800'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:34:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'mg (mg)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:34:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered empty.	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:34:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'twice daily (BID)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:34:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered empty.	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:34:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'Oral (ORAL)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:34:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered empty.	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:34:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered '10 Nov 2020'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:34:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered '0'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:34:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:34:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered empty.	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:34:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:34:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Nov 2020 17:34:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Nov 2020 17:34:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Nov 2020 17:34:38

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:42:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 01:30:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 01:30:16
Data point term sent to Coder	System	24 Nov 2020 18:53:16
User closed query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	System	24 Nov 2020 18:52:27
Query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' answered with 'this was already done (ASPIRIN)' (Site from System).	Elissa Malkin (b) (4)	24 Nov 2020 18:52:27
User opened query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	Coder Import (b) (4)	23 Nov 2020 09:36:08
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
Data point term sent to Coder	System	13 Nov 2020 17:36:06
User entered 'BC Powder (aspirin)'	Erika Faust (b) (4)	13 Nov 2020 17:35:26

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:42:26
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'No (N)'	Erika Faust (b) (4)	13 Nov 2020 17:35:26

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:42:26
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'Headache'	Erika Faust (b) (4)	13 Nov 2020 17:35:26

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:42:26
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'l'	Erika Faust (b) (4)	13 Nov 2020 17:35:26

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:42:26
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'Other (OTHER)'	Erika Faust (b) (4)	13 Nov 2020 17:35:26

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:42:26
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'packet'	Erika Faust (b) (4)	13 Nov 2020 17:35:26

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:42:26
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'twice daily (BID)'	Erika Faust (b) (4)	13 Nov 2020 17:35:26

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:42:26
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered empty.	Erika Faust (b) (4)	13 Nov 2020 17:35:26

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:42:26
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'Oral (ORAL)'	Erika Faust (b) (4)	13 Nov 2020 17:35:26

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:13

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:42:26
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered empty.	Erika Faust (b) (4)	13 Nov 2020 17:35:26

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:42:26
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered '23 Oct 2020'	Erika Faust (b) (4)	13 Nov 2020 17:35:26

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:42:26
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered '0'	Erika Faust (b) (4)	13 Nov 2020 17:35:26

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:42:26
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'No (N)'	Erika Faust (b) (4)	13 Nov 2020 17:35:26

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:42:26
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered '25 Oct 2020'	Erika Faust (b) (4)	13 Nov 2020 17:35:26

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:42:26
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'No (N)'	Erika Faust (b) (4)	13 Nov 2020 17:35:26

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:42:26
User entered '2'	System	13 Nov 2020 17:35:26

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:42:26
User entered 'I'	System	13 Nov 2020 17:35:26

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:42:26
User entered '804 (804)'	System	13 Nov 2020 17:35:26

US3542168

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:08:13

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:37:18
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	03 Feb 2021 20:02:18

US3542168

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:08:13

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:30:14
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:46:00
User entered '08 Oct 2020'	Hannah Yellin (b) (4)	19 Oct 2020 19:32:56

US3542168

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:08:13

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:30:14
User closed query 'Per CDM: reason for discontinuation is recorded as PI decision relating to hospital admissions for psychiatric reason; however there is no adverse event recorded for this other than Exacerbation of Anxiety. Please review and consider updating AE form appropriately with action to IP as IP Withdrawn and update this page accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 11:03:54
Query 'Per CDM: reason for discontinuation is recorded as PI decision relating to hospital admissions for psychiatric reason; however there is no adverse event recorded for this other than Exacerbation of Anxiety. Please review and consider updating AE form appropriately with action to IP as IP Withdrawn and update this page accordingly.' answered with 'AE form updated with IP withdrawn. It was the PI decision to discontinue dosing as a result of 2 AEs that occurred close temporally' (Site from DM).	Elissa Malkin (b) (4) (b) (4)	24 Nov 2020 18:32:56
User opened query 'Per CDM: reason for discontinuation is recorded as PI decision relating to hospital admissions for psychiatric reason; however there is no adverse event recorded for this other than Exacerbation of Anxiety. Please review and consider updating AE form appropriately with action to IP as IP Withdrawn and update this page accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:12:52
Query 'Per CDM: reason for discontinuation is recorded as PI decision relating to hospital admissions for psychiatric reason; however there is no adverse event recorded for this other than Exacerbation of Anxiety. Please review and consider updating AE form appropriately with action to IP as IP Withdrawn and update this page accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:12:39

US3542168

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:08:13

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: reason for discontinuation is recorded as PI decision relating to hospital admissions for psychiatric reason; however there si no adverse event recorded for this other than Exacerbation of Anxiety. Please review and consider updating AE form appropriately with action to IP as IP Withdrawn and update this page accordingly.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	18 Nov 2020 16:11:54
	David Diemert (b) (4)	21 Oct 2020 18:46:00
User entered 'Physician decision (specify) (PHYSICIAN DECISION)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	19 Oct 2020 19:32:56

US3542168

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:08:13

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 08:30:14
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:46:00
User entered 'Physician withheld dose due to hospital admissions for psychiatric reasons'	Hannah Yellin (b) (4)	19 Oct 2020 19:32:56

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'USA-US084-2020-MRNA-1273-P301000001'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Yes (Y)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Yes (Y)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'David'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Diemert'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered '2300 Eye Street NW'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Washington'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'DC'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered '20037'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:00:57
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'US'	(b) (4) System	20 Sep 2020 17:53:12

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:57:53
	(b) (4)	
Signature has been broken.	System	23 Nov 2020 14:38:41
User entered '5'	System	23 Nov 2020 14:38:41
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:28:16
	(b) (4)	
Signature has been broken.	System	28 Oct 2020 18:06:27
User entered '4'	System	28 Oct 2020 18:06:27
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
	(b) (4)	
Signature has been broken.	System	30 Sep 2020 17:33:06
User entered '3'	System	30 Sep 2020 17:33:06
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:31:49
	(b) (4)	
Signature has been broken.	System	28 Sep 2020 14:01:09
User entered '2'	System	28 Sep 2020 14:01:09
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
	(b) (4)	
User entered '1'	System	20 Sep 2020 17:53:12

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'USA-US084-2020-MRNA-1273-P301000001'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Yes (Y)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Yes (Y)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'David'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Diemert'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered '2300 Eye Street NW'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Washington'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'DC'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered '20037'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:00:57
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'US'	(b) (4) System	20 Sep 2020 17:53:12

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:57:53
	(b) (4)	
Signature has been broken.	System	23 Nov 2020 14:38:41
User entered '5'	System	23 Nov 2020 14:38:41
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:28:16
	(b) (4)	
Signature has been broken.	System	28 Oct 2020 18:06:27
User entered '4'	System	28 Oct 2020 18:06:27
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
	(b) (4)	
Signature has been broken.	System	30 Sep 2020 17:33:06
User entered '3'	System	30 Sep 2020 17:33:06
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:31:49
	(b) (4)	
Signature has been broken.	System	28 Sep 2020 14:01:09
User entered '2'	System	28 Sep 2020 14:01:09
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
	(b) (4)	
User entered '1'	System	20 Sep 2020 17:53:12

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:08:13

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '20/Sep/2020 13:53'	(b) (4) System	20 Sep 2020 17:53:12

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:08:13

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)	23 Nov 2020 15:21:28
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:00:57
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'I'	(b) (4), (b) (6)	20 Sep 2020 17:53:12

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'USA-US084-2020-MRNA-1273-P301000001'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Yes (Y)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Yes (Y)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'David'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Diemert'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered '2300 Eye Street NW'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Washington'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'DC'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered '20037'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:00:57
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'US'	(b) (4) System	20 Sep 2020 17:53:12

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:57:53
	(b) (4)	
Signature has been broken.	System	23 Nov 2020 14:38:41
User entered '5'	System	23 Nov 2020 14:38:41
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:28:16
	(b) (4)	
Signature has been broken.	System	28 Oct 2020 18:06:27
User entered '4'	System	28 Oct 2020 18:06:27
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
	(b) (4)	
Signature has been broken.	System	30 Sep 2020 17:33:06
User entered '3'	System	30 Sep 2020 17:33:06
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:31:49
	(b) (4)	
Signature has been broken.	System	28 Sep 2020 14:01:09
User entered '2'	System	28 Sep 2020 14:01:09
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
	(b) (4)	
User entered '1'	System	20 Sep 2020 17:53:12

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:08:13

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:31:49
User entered '28/Sep/2020 10:01'	(b) (4) System	28 Sep 2020 14:01:09

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:08:13

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)	23 Nov 2020 15:21:28
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:32:52
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:31:49
User entered 'I'	(b) (4), (b) (6)	28 Sep 2020 14:01:09

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'USA-US084-2020-MRNA-1273-P301000001'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Yes (Y)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Yes (Y)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'David'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Diemert'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered '2300 Eye Street NW'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Washington'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'DC'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered '20037'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:00:57
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'US'	(b) (4) System	20 Sep 2020 17:53:12

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:57:53
	(b) (4)	
Signature has been broken.	System	23 Nov 2020 14:38:41
User entered '5'	System	23 Nov 2020 14:38:41
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:28:16
	(b) (4)	
Signature has been broken.	System	28 Oct 2020 18:06:27
User entered '4'	System	28 Oct 2020 18:06:27
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
	(b) (4)	
Signature has been broken.	System	30 Sep 2020 17:33:06
User entered '3'	System	30 Sep 2020 17:33:06
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:31:49
	(b) (4)	
Signature has been broken.	System	28 Sep 2020 14:01:09
User entered '2'	System	28 Sep 2020 14:01:09
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
	(b) (4)	
User entered '1'	System	20 Sep 2020 17:53:12

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:08:13

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '30/Sep/2020 17:33'	(b) (4) System	30 Sep 2020 17:33:06

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:08:13

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)	23 Nov 2020 15:21:28
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 18:06:16
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered 'I'	(b) (4), (b) (6)	30 Sep 2020 17:33:06

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'USA-US084-2020-MRNA-1273-P301000001'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Yes (Y)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Yes (Y)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'David'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Diemert'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered '2300 Eye Street NW'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Washington'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'DC'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered '20037'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:00:57
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'US'	(b) (4) System	20 Sep 2020 17:53:12

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:57:53
	(b) (4)	
Signature has been broken.	System	23 Nov 2020 14:38:41
User entered '5'	System	23 Nov 2020 14:38:41
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:28:16
	(b) (4)	
Signature has been broken.	System	28 Oct 2020 18:06:27
User entered '4'	System	28 Oct 2020 18:06:27
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
	(b) (4)	
Signature has been broken.	System	30 Sep 2020 17:33:06
User entered '3'	System	30 Sep 2020 17:33:06
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:31:49
	(b) (4)	
Signature has been broken.	System	28 Sep 2020 14:01:09
User entered '2'	System	28 Sep 2020 14:01:09
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
	(b) (4)	
User entered '1'	System	20 Sep 2020 17:53:12

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:08:13

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:28:16
User entered '28/Oct/2020 14:06'	(b) (4) System	28 Oct 2020 18:06:27

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:08:13

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)	23 Nov 2020 15:21:28
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 14:38:28
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:28:16
User entered 'I'	(b) (4), (b) (6)	28 Oct 2020 18:06:27

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'USA-US084-2020-MRNA-1273-P301000001'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Yes (Y)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Yes (Y)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'David'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Diemert'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered '2300 Eye Street NW'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Washington'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'DC'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered '20037'	System	20 Sep 2020 17:52:47

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:00:57
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'US'	(b) (4) System	20 Sep 2020 17:53:12

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:57:53
	(b) (4)	
Signature has been broken.	System	23 Nov 2020 14:38:41
User entered '5'	System	23 Nov 2020 14:38:41
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:28:16
	(b) (4)	
Signature has been broken.	System	28 Oct 2020 18:06:27
User entered '4'	System	28 Oct 2020 18:06:27
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
	(b) (4)	
Signature has been broken.	System	30 Sep 2020 17:33:06
User entered '3'	System	30 Sep 2020 17:33:06
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:31:49
	(b) (4)	
Signature has been broken.	System	28 Sep 2020 14:01:09
User entered '2'	System	28 Sep 2020 14:01:09
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
	(b) (4)	
User entered '1'	System	20 Sep 2020 17:53:12

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:08:13

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:57:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:21:28
User entered '23/Nov/2020 09:38'	System	23 Nov 2020 14:38:41

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:08:13

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)	01 Dec 2020 16:57:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:21:28
User entered 'I'	(b) (4), (b) (6)	23 Nov 2020 14:38:41