

US3542108 (Prod: George Washington University)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:06:32

All time stamps listed in this document are displayed in GMT

US3542108

Form: Participant Creation

Data signed: (b) (4) 05 Sep 2020 21:37:16

Generated On: 10 Jun 2021 08:06:32

Participant ID

US3542108

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

US3542108

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Sep 2020 21:37:17

Generated On: 10 Jun 2021 08:06:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 24 Sep 2020 03:17:32

Generated On: 10 Jun 2021 08:06:32

Date of Birth (MMM yyyy)	(b) (6) 1974
Age	46
Age Units	YEARS
Age (Derived)	46
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 05 Sep 2020 21:37:17

Generated On: 10 Jun 2021 08:06:32

Date of Informed Consent (<i>dd MMM yyyy</i>)	31 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input 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

US3542108

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 05 Sep 2020 21:37:17

Generated On: 10 Jun 2021 08:06:32

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 05 Sep 2020 21:37:17

Generated On: 10 Jun 2021 08:06:32

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 22 Dec 2020 22:02:38

Generated On: 10 Jun 2021 08:06:32

Condition	C SECTION
Start date (dd MMM yyyy)	13 OCT 2005
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)	13 OCT 2005
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2005
Start Year (derived)	2005
Stop Month and Year (derived)	OCT 2005
Stop Year (derived)	2005

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 22 Dec 2020 22:02:38

Generated On: 10 Jun 2021 08:06:32

Condition	C SECTION
Start date (dd MMM yyyy)	30 JUN 2008
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)	30 JUN 2008
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JUN 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 22 Dec 2020 22:02:38

Generated On: 10 Jun 2021 08:06:32

Condition	MASTECTOMY - FLAP RECONSTRUCTION
Start date (dd MMM yyyy)	UN APR 2017
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 APR 2017
Stop date completely unknown	False
Start Month and Year (derived)	APR 2017
Start Year (derived)	2017
Stop Month and Year (derived)	APR 2017
Stop Year (derived)	2017

US3542108

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 22 Dec 2020 22:02:38

Generated On: 10 Jun 2021 08:06:32

Condition	ANXIETY
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)	

US3542108

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 22 Dec 2020 22:02:38

Generated On: 10 Jun 2021 08:06:32

Condition	DERMAL FILLER (VOLUMA) CHEEK INJECTIONS, BILATERL
Start date (dd MMM yyyy)	UN MAR 2020
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 MAR 2020
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	MAR 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Sep 2020 21:37:17

Generated On: 10 Jun 2021 08:06:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	14:45 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 14:45
Height (xxx.x)	63 in
Weight (xxx.x)	108 lb
BMI (xxx.x)	19.17134 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) 27 Dec 2020 23:00:34

Generated On: 10 Jun 2021 08:06:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 05 Sep 2020 21:37:16

Generated On: 10 Jun 2021 08:06:32

Date of assessment (dd MMM yyyy) 31 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify NOT INDICATED

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

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Sep 2020 04:24:45

Generated On: 10 Jun 2021 08:06:32

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

DIRECTOR OF (b) (6)

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Sep 2020 04:24:45

Generated On: 10 Jun 2021 08:06:32

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)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 05 Sep 2020 21:37:17

Generated On: 10 Jun 2021 08:06:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Oct 2020 02:53:34

Generated On: 10 Jun 2021 08:06:32

What was the date of randomization? (dd MMM yyyy) 31 AUG 2020

What was the participant's randomization number? 110309

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) 05 Sep 2020 21:37:17

Generated On: 10 Jun 2021 08:06:32

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) 05 Sep 2020 21:37:17

Generated On: 10 Jun 2021 08:06:32

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)	31 AUG 2020
Time of assessment (00:00-23:59)	14:45 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 14:45
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)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Sep 2020 21:37:17

Generated On: 10 Jun 2021 08:06:32

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)	31 AUG 2020
Time of assessment (00:00-23:59)	16:05 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 16:05
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 27 Dec 2020 23:00:34

Generated On: 10 Jun 2021 08:06:32

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) 05 Sep 2020 21:37:17

Generated On: 10 Jun 2021 08:06:32

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) 31 AUG 2020

What was the treatment time? (00:00-23:59) 15:30 (24 HR)

Treatment Date and Time (derived) 31 AUG 2020 15:30

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) 05 Sep 2020 21:37:17

Generated On: 10 Jun 2021 08:06:32

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	31 AUG 2020
Collection time (00:00-23:59)	14:45 (24 HR)
Collection date and time (derived)	31 AUG 2020 14:45

US3542108

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Sep 2020 21:37:17

Generated On: 10 Jun 2021 08:06:32

Collection date (dd MMM yyyy)			31 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:50	31 AUG 2020 14:50
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 05 Sep 2020 21:37:17

Generated On: 10 Jun 2021 08:06:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

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

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

31 AUG 2020 16:07

PC Open Date & Time

31 AUG 2020 15:50

PC Close Date & Time

31 AUG 2020 18:20

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 19:34

PC Open Date & Time

31 AUG 2020 19:15

PC Close Date & Time

01 SEP 2020 11:59

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:06:32

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 21:32

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

02 SEP 2020 19:14

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

03 SEP 2020 21:31

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:06:32

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

04 SEP 2020 23:53

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

05 SEP 2020 20:16

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

06 SEP 2020 21:54

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

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

31 AUG 2020 16:08

PC Open Date & Time

31 AUG 2020 15:50

PC Close Date & Time

31 AUG 2020 18:20

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

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

31 AUG 2020 19:35

PC Open Date & Time

31 AUG 2020 19:15

PC Close Date & Time

01 SEP 2020 11:59

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:32

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

01 SEP 2020 21:33

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:32

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

02 SEP 2020 19:14

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:32

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

03 SEP 2020 21:32

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:32

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

04 SEP 2020 23:53

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:32

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

05 SEP 2020 20:17

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:32

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

06 SEP 2020 21:55

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

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 ☐

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 16:08
PC Open Date & Time	31 AUG 2020 15:50
PC Close Date & Time	31 AUG 2020 18:20

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

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 ☐

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 19:35
PC Open Date & Time	31 AUG 2020 19:15
PC Close Date & Time	01 SEP 2020 11:59

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:32

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 21:34
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:32

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 19:15
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:32

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 ☒

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:32

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 21:32
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:32

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

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EAB) (1725)

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:32

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 23:54
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

55 of 1881

EAB) (1725)

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:32

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 20:18
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:32

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 ☒

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EAB) (1725)

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US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:32

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 21:55
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3542108

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 14 Sep 2020 04:56:42

Generated On: 10 Jun 2021 08:06:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542108

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 14 Sep 2020 04:56:42

Generated On: 10 Jun 2021 08:06:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542108

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 24 Sep 2020 03:17:32

Generated On: 10 Jun 2021 08:06:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542108

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 29 Sep 2020 04:23:31

Generated On: 10 Jun 2021 08:06:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542108

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 29 Sep 2020 04:23:31

Generated On: 10 Jun 2021 08:06:32

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3542108

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 29 Sep 2020 04:23:31

Generated On: 10 Jun 2021 08:06:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542108

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 30 Sep 2020 22:42:54

Generated On: 10 Jun 2021 08:06:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3542108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 30 Sep 2020 22:42:54

Generated On: 10 Jun 2021 08:06:32

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)	29 SEP 2020
Time of assessment (00:00-23:59)	10:00 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 10:00
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3542108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 30 Sep 2020 22:42:54

Generated On: 10 Jun 2021 08:06:32

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)	29 SEP 2020
Time of assessment (00:00-23:59)	11:30 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 11:30
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)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3542108

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 30 Sep 2020 22:42:54

Generated On: 10 Jun 2021 08:06:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

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

US3542108

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 30 Sep 2020 22:42:54

Generated On: 10 Jun 2021 08:06:32

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) 29 SEP 2020

What was the treatment time? (00:00-23:59) 10:57 (24 HR)

Treatment Date and Time (derived) 29 SEP 2020 10:57

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

What was the frequency of the study treatment dosing? ONCE

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

US3542108

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Sep 2020 22:42:54

Generated On: 10 Jun 2021 08:06:32

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 SEP 2020
Collection time (00:00-23:59)	10:15 (24 HR)
Collection date and time (derived)	29 SEP 2020 10:15

US3542108

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 30 Sep 2020 22:42:54

Generated On: 10 Jun 2021 08:06:32

Collection date (dd MMM yyyy)			29 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:20	29 SEP 2020 10:20
Nasopharyngeal Swab 2	No		

US3542108

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 30 Sep 2020 22:42:54

Generated On: 10 Jun 2021 08:06:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

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

98.4 °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

29 SEP 2020 11:33

PC Open Date & Time

29 SEP 2020 11:17

PC Close Date & Time

29 SEP 2020 13:47

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °F

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

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

PC Time Stamp	29 SEP 2020 21:02
PC Open Date & Time	29 SEP 2020 14:42
PC Close Date & Time	30 SEP 2020 11:59

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:06:32

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

97.7 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

30 SEP 2020 16:04

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:06:32

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	01 OCT 2020 19:00
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:06:32

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	False
To PREVENT pain or fever from occurring	True
PC Time Stamp	03 OCT 2020 00:20
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:06:32

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	False
To PREVENT pain or fever from occurring	True

PC Time Stamp	04 OCT 2020 05:47
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 22:10

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 21:37

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

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

29 SEP 2020 11:33

PC Open Date & Time

29 SEP 2020 11:17

PC Close Date & Time

29 SEP 2020 13:47

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

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

29 SEP 2020 21:03

PC Open Date & Time

29 SEP 2020 14:42

PC Close Date & Time

30 SEP 2020 11:59

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:32

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

30 SEP 2020 16:05

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:32

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

01 OCT 2020 19:01

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:32

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

03 OCT 2020 00:20

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:32

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

04 OCT 2020 05:47

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:32

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

04 OCT 2020 22:11

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:32

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

05 OCT 2020 21:37

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

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 ☐

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 11:33
PC Open Date & Time	29 SEP 2020 11:17
PC Close Date & Time	29 SEP 2020 13:47

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

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 ☐

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 21:03
PC Open Date & Time	29 SEP 2020 14:42
PC Close Date & Time	30 SEP 2020 11:59

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☒

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☒

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:32

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 16:06
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☒

Prevents daily activity and
requires medical attention ☐

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

No ☐

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US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:32

		Yes <input type="checkbox"/>
PC Time stamp	01 OCT 2020 19:00	
PC Open Date & Time	01 OCT 2020 12:00	
PC Close Date & Time	02 OCT 2020 11:59	

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:32

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 ☒

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US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:32

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 00:21
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:32

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 ☐

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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:32

		Yes <input type="checkbox"/>
PC Time stamp	04 OCT 2020 05:47	
PC Open Date & Time	03 OCT 2020 12:00	
PC Close Date & Time	04 OCT 2020 11:59	

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:32

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 ☐

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:32

		Yes <input type="checkbox"/>
PC Time stamp	04 OCT 2020 22:11	
PC Open Date & Time	04 OCT 2020 12:00	
PC Close Date & Time	05 OCT 2020 11:59	

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:32

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 ☐

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Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:32

		Yes <input type="checkbox"/>
PC Time stamp	05 OCT 2020 21:38	
PC Open Date & Time	05 OCT 2020 12:00	
PC Close Date & Time	06 OCT 2020 11:59	

US3542108

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp 07 OCT 2020 00:03

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59

US3542108

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

DAY 8

Select one response below to indicate the level of your

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 ☐

PC Time stamp 07 OCT 2020 00:03

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59

US3542108

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	07 OCT 2020 00:03
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3542108

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 08 Oct 2020 03:01:20

Generated On: 10 Jun 2021 08:06:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542108

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 08 Oct 2020 03:01:20

Generated On: 10 Jun 2021 08:06:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542108

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Oct 2020 02:53:34

Generated On: 10 Jun 2021 08:06:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542108

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Oct 2020 02:53:34

Generated On: 10 Jun 2021 08:06:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542108

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Oct 2020 13:50:13

Generated On: 10 Jun 2021 08:06:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542108

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Oct 2020 13:50:13

Generated On: 10 Jun 2021 08:06:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542108

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 30 Oct 2020 01:19:06

Generated On: 10 Jun 2021 08:06:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3542108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Oct 2020 01:19:06

Generated On: 10 Jun 2021 08:06:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 OCT 2020
Time of assessment (00:00-23:59)	11:16 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 11:16
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3542108

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 30 Oct 2020 01:19:06

Generated On: 10 Jun 2021 08:06:32

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.

US3542108

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Oct 2020 01:19:06

Generated On: 10 Jun 2021 08:06:32

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 OCT 2020
Collection time (00:00-23:59)	11:24 (24 HR)
Collection date and time (derived)	27 OCT 2020 11:24

US3542108

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 30 Oct 2020 01:19:06

Generated On: 10 Jun 2021 08:06:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	01 NOV 2020 17:33:16
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2020 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

[Patient Cloud Close Date & Time](#)

06 DEC 2020 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

[Patient Cloud Close Date & Time](#)

13 DEC 2020 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

[Patient Cloud Close Date & Time](#)

27 DEC 2020 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 JAN 2021 10:35:13

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 JAN 2021 11:37:26

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 09:52:56

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 11:57:13

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 JAN 2021 11:07:31

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 09:46:27

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 FEB 2021 09:33:18

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 FEB 2021 18:50:59

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 FEB 2021 15:32:13

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 MAR 2021 22:49:13
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 MAR 2021 08:54:15
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 11:59:30

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 MAR 2021 10:58:53

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 12:07:05

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 08:51:44

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 07:56:10

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 19:51:54

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 23:11:40

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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 ☐

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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 ☐

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2021 00:01
Patient Cloud Close Date & Time	18 JUL 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2021 00:01
Patient Cloud Close Date & Time	25 JUL 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

[Patient Cloud Open Date & Time](#)

25 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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 ☐

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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 ☐

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2021 00:01
Patient Cloud Close Date & Time	24 OCT 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2021 00:01
Patient Cloud Close Date & Time	31 OCT 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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 ☐

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

[Patient Cloud Close Date & Time](#)

19 DEC 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	22 DEC 2021 00:01
Patient Cloud Close Date & Time	26 DEC 2021 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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 ☐

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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 <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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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 ☐

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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 ☐

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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 ☐

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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 ☐

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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 ☐

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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 ☐

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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 ☐

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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 ☐

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 APR 2022 00:01
Patient Cloud Close Date & Time	24 APR 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	22 JUN 2022 00:01
Patient Cloud Close Date & Time	26 JUN 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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 ☐

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2022 00:01
Patient Cloud Close Date & Time	10 JUL 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

14 AUG 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

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Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 SEP 2022 00:01
Patient Cloud Close Date & Time	25 SEP 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

[Patient Cloud Close Date & Time](#)

23 OCT 2022 23:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2022 00:01
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Patient Cloud Close Date & Time	30 OCT 2022 23:59
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US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

US3542108

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:06:32

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
Yes	No	02 MAR 2021 16:51:42

US3542108

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 01 Dec 2020 16:57:25

Generated On: 10 Jun 2021 08:06:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542108

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 01 Dec 2020 16:57:25

Generated On: 10 Jun 2021 08:06:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542108

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 08 Jan 2021 03:22:12

Generated On: 10 Jun 2021 08:06:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542108

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 08 Jan 2021 03:22:12

Generated On: 10 Jun 2021 08:06:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542108

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 31 Jan 2021 19:19:25

Generated On: 10 Jun 2021 08:06:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542108

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 31 Jan 2021 19:19:25

Generated On: 10 Jun 2021 08:06:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542108

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 20:11:37

Generated On: 10 Jun 2021 08:06:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542108

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:11:37

Generated On: 10 Jun 2021 08:06:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542108

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 16:51:53

Generated On: 10 Jun 2021 08:06:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 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	VISIT4

US3542108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 21:16:03

Generated On: 10 Jun 2021 08:06:32

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) _____

US3542108

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 16:51:53

Generated On: 10 Jun 2021 08:06:32

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.

US3542108

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 16:51:53

Generated On: 10 Jun 2021 08:06:32

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 MAR 2021
Collection time (00:00-23:59)	10:28 (24 HR)
Collection date and time (derived)	25 MAR 2021 10:28

US3542108

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 16:51:53

Generated On: 10 Jun 2021 08:06:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542108

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

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

US3542108

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:32

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3542108

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:06:32

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"/>

US3542108

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:06:32

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3542108

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

Form: Visit Date

Data signed: (b) (4) 04 Feb 2021 22:34:05

Generated On: 10 Jun 2021 08:06:32

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

Visit date (dd MMM yyyy)	02 FEB 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3542108

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

Form: Unblinding

Data signed: (b) (4) 12 Mar 2021 22:43:00

Generated On: 10 Jun 2021 08:06:32

Date of updated informed consent (dd MMM yyyy) 02 FEB 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 02 FEB 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3542108

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Feb 2021 22:34:05

Generated On: 10 Jun 2021 08:06:32

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	02 FEB 2021
Collection time (00:00-23:59)	11:16 (24 HR)
Collection date and time (derived)	02 FEB 2021 11:16

US3542108

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 04 Feb 2021 22:34:05

Generated On: 10 Jun 2021 08:06:32

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	02 FEB 2021
Collection time (00:00 - 23:59)	11:20
Collection Date and Time (derived)	02 FEB 2021 11:20

US3542108

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 08 Oct 2020 03:01:20

Generated On: 10 Jun 2021 08:06:32

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3542108

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 01 Dec 2020 16:57:24

Generated On: 10 Jun 2021 08:06:32

AEID	USA-US084-2020-MRNA-1273-P30 1000003
Adverse event	CHEEK SWELLING, BILATERAL
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)	30 SEP 2020
Start time (00:00-23:59)	10:00 (24 HR)
AE start date and time (derived)	30 SEP 2020 10:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	05 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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	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"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 01 Dec 2020 16:57:24

Generated On: 10 Jun 2021 08:06:32

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

US3542108

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 01 Dec 2020 16:57:24

Generated On: 10 Jun 2021 08:06:32

46 YEAR OLD FEMALE
ENROLLED AND RECEIVED 1ST
DOSE OF VACCINE/PLACEBO
ON 31AUG2020; 2ND DOSE
ADMINISTERED ON 29SEP2020.
STARTING NIGHT OF 29SEP2020
HAD INJECTION SITE PAIN,
THROUGH 30SEP2020. ALSO
MODERATE MYALGIAS &
ARTHRALGIAS
30SEP-01OCT2020. AWOKE
30SEP2020 WITH SIGNIFICANT
BILATERAL CHEEK SWELLING;
NO RASH, PAIN, TENDERNESS,
ORAL OR RESPIRATORY
SYMPTOMS. NO FEVER/CHILLS.
FELT ABSOLUTELY WELL
ASIDE FROM UNSIGHTLY
CHEEK SWELLING. NO NEW
MEDS, FOODS, CREAMS,
TOOTHPASTE, ETC. OF NOTE,
HAD BILATERAL VOLUMA
CHEEK INJECTIONS IN MARCH
2020 (FIRST AND ONLY
ADMINISTRATION), WITHOUT
INCIDENT.
NO RELIEF FROM BENADRYL
(50MG QD 01-03OCT2020). DUE
TO ONGOING SWELLING,
STARTED ON SOLUMEDROL
DOSE PACK (4MG TABS) ON
03OCT2020 (THROUGH
07OCT2020). CONSIDERABLY
IMPROVED BY 04OCT2020 WITH
COMPLETE

US3542108

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 01 Dec 2020 16:57:24

Generated On: 10 Jun 2021 08:06:32

RESOLUTION OF SWELLING BY
05OCT2020. NO RECURRENCE.
WAS NOT ORIGINALLY
REPORTED AS AN SAE BUT DUE
TO RECENT MEDWATCH
REPORT (MOD-2020-000515,
PARTICIPANT US3322329) OF A
VERY SIMILAR EVENT IN
ANOTHER STUDY PARTICIPANT
POST-VOLUMA FILLER
INJECTION, I AM NOW
SUBMITTING THIS EVENT AS
AN UNEXPECTED, RELATED
SAE (IN MY CLINICAL
JUDGEMENT).

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)	
--	--

US3542108

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 01 Dec 2020 16:57:24

Generated On: 10 Jun 2021 08:06:32

AEID

Adverse event

OCULAR PRURITUS

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)

17 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)

17 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 (2)

Data signed: (b) (4) 01 Dec 2020 16:57:24

Generated On: 10 Jun 2021 08:06:32

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)	_____

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Sep 2020 21:37:16

Generated On: 10 Jun 2021 08:06:32

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

Yes ☒

No ☐

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

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Dec 2020 22:17:58

Generated On: 10 Jun 2021 08:06:32

Name of Medication CYMBALTA

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 60

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) 22 Dec 2020 22:17:58

Generated On: 10 Jun 2021 08:06:32

	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) 22 Dec 2020 22:17:58

Generated On: 10 Jun 2021 08:06:32

Name of Medication BENADRYL

Prophylaxis Yes ☐
No ☒

Indication CHEEK SWELLING

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Dec 2020 22:17:58

Generated On: 10 Jun 2021 08:06:32

	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)		01 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)		03 OCT 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) 22 Dec 2020 22:17:58

Generated On: 10 Jun 2021 08:06:32

Name of Medication SOLUMEDROL DOSE PAK

Prophylaxis Yes ☐
No ☒

Indication CHEEK SWELLING

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

20MG ON DAY 1
16MG ON DAY 2
12MG ON DAY 3
8MG ON DAY 4
4MG ON DAY 5

Route of administration Oral ☒
Topical ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Dec 2020 22:17:58

Generated On: 10 Jun 2021 08:06:32

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	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"/>
<hr/>		
If route of administration is Other, specify _____		
<hr/>		
Start date (dd MMM yyyy)	03 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
<hr/>		
If not Ongoing, End date (dd MMM yyyy)	7 OCT 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
<hr/>		
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 (4)

Data signed: (b) (4) 22 Dec 2020 22:17:58

Generated On: 10 Jun 2021 08:06:32

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication HEADACHE AND MYALGIAS

Dose per administration 650

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) 22 Dec 2020 22:17:58

Generated On: 10 Jun 2021 08:06:32

	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)	30 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)		03 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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 (5)

Data signed: (b) (4) 22 Dec 2020 22:17:58

Generated On: 10 Jun 2021 08:06:32

Name of Medication BENADRYL

Prophylaxis Yes ☐
No ☒

Indication OCULAR PRURITUS

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Dec 2020 22:17:58

Generated On: 10 Jun 2021 08:06:32

	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)		17 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)		17 OCT 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 (6)

Data signed: (b) (4) 22 Dec 2020 22:17:58

Generated On: 10 Jun 2021 08:06:32

Name of Medication INFLUENZA VACCINATION

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Dec 2020 22:17:58

Generated On: 10 Jun 2021 08:06:32

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		26 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3542108

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 04 Feb 2021 22:34:05

Generated On: 10 Jun 2021 08:06:32

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3542108

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:06:32

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3542108

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:06:32

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 ☐

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 21 Nov 2020 16:52:01

Generated On: 10 Jun 2021 08:06:32

SAEID	USA-US084-2020-MRNA-1273-P301000003
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input 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)	2

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 21 Nov 2020 16:52:01

Generated On: 10 Jun 2021 08:06:32

SAEID	USA-US084-2020-MRNA-1273-P301000003
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input 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)	2
Date of submission (Pre-filled from custom function)	06/NOV/2020 16:57
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 21 Nov 2020 16:52:01

Generated On: 10 Jun 2021 08:06:32

SAEID	USA-US084-2020-MRNA-1273-P301000003
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input 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)	2
Date of submission (Pre-filled from custom function)	21/NOV/2020 16:02
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

US3542108 (Prod: George Washington University)

US3542108

Form: Participant Creation

Generated On: 10 Jun 2021 08:06:32

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:56:33
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'US3542108'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 18:29:29

US3542108

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:06:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'Yes (Y)'	(b) (4) Elissa Malkin (b) (4)	31 Aug 2020 18:30:14

US3542108

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '31 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 18:29:30

US3542108

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'Clinic (Clinic)'	(b) (4) Elissa Malkin (b) (4) (b) (4)	31 Aug 2020 18:30:14

US3542108

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:06:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered 'SCRN'	System	31 Aug 2020 18:30:14

US3542108

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:32

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered (b) (6) 1974'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 18:29:31

US3542108

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:32

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '46'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:23:55

US3542108

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:32

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered 'YEARS'	System	01 Sep 2020 20:23:55

US3542108

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:32

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered '46'	System	31 Aug 2020 18:30:32

US3542108

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:32

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'Female (F)'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:23:55

US3542108

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:32

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:17:32
Signature has been broken.	(b) (4)	
	Hannah Yellin (b) (4)	17 Sep 2020 17:38:55
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' reason for change: New Information	Hannah Yellin (b) (4)	17 Sep 2020 17:38:55
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
	(b) (4)	
User entered 'Not Reported (NOT REPORTED)'	Madhu Balachandran	01 Sep 2020 20:23:55
	(b) (4)	

US3542108

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:32

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'I'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:23:55

US3542108

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:32

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:23:55

US3542108

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:32

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:23:55

US3542108

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:32

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:23:55

US3542108

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:32

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:23:55

US3542108

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:32

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:23:55

US3542108

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:32

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:23:55

US3542108

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:32

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:23:55

US3542108

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:32

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:23:55

US3542108

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:06:32

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '31 Aug 2020'	(b) (4) Elissa Malkin (b) (4)	31 Aug 2020 18:30:32

US3542108

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered 'Aug 2020'	System	31 Aug 2020 18:30:32

US3542108

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered '2020'	System	31 Aug 2020 18:30:32

US3542108

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:06:32

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'Amendment 3 (3)'	(b) (4) Elissa Malkin (b) (4) (b) (4)	31 Aug 2020 18:30:32

US3542108

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'Yes (Y)'	(b) (4) Elissa Malkin (b) (4)	31 Aug 2020 18:30:32

US3542108

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered empty.	(b) (4) Elissa Malkin (b) (4) (b) (4)	31 Aug 2020 18:30:32

US3542108

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:06:32

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered empty.	(b) (4) Elissa Malkin (b) (4) (b) (4)	31 Aug 2020 18:30:32

US3542108

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:06:32

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'No (N)'	(b) (4) Elissa Malkin (b) (4)	31 Aug 2020 18:30:32

US3542108

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:06:32

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 18:29:30

US3542108

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:06:32

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered 'l'	System	31 Aug 2020 18:30:38

US3542108

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'Yes (Y)'	(b) (4) Elissa Malkin (b) (4)	31 Aug 2020 18:30:38

US3542108

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:06:32

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:14:43

US3542108

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:06:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: C-section - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 20:16:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 20:16:44
Data point term sent to Coder	System	01 Sep 2020 20:15:46
User entered 'C section'	Madhu Balachandran (b) (4)	01 Sep 2020 20:15:05

US3542108

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '13 Oct 2005'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:15:05

US3542108

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:06:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:15:05

US3542108

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:06:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 11:38:08
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'Updated.' (Site from DM).	David Diemert (b) (4)	29 Oct 2020 20:54:13
Signature has been broken.	David Diemert (b) (4)	29 Oct 2020 20:54:01
User entered 'No (N)' reason for change: Per Query Resolution	David Diemert (b) (4)	29 Oct 2020 20:54:01
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 06:16:46
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	01 Sep 2020 20:15:05

US3542108

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	29 Oct 2020 20:54:01
	(b) (4)	
User entered '13 Oct 2005' reason for change: Data Entry Error	David Diemert (b) (4)	29 Oct 2020 20:54:01
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	05 Sep 2020 21:37:17
	(b) (4)	
User entered empty.	Madhu Balachandran	01 Sep 2020 20:15:05
	(b) (4)	

US3542108

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:06:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:15:05

US3542108

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered 'Oct 2005'	System	01 Sep 2020 20:15:05

US3542108

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered '2005'	System	01 Sep 2020 20:15:05

US3542108

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered 'Oct 2005'	System	29 Oct 2020 20:54:01
User entered empty.	System	01 Sep 2020 20:15:05

US3542108

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered '2005'	System	29 Oct 2020 20:54:01
User entered empty.	System	01 Sep 2020 20:15:05

US3542108

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:06:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 11:38:37
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'Updated.' (Site from DM).	David Diemert (b) (4)	29 Oct 2020 20:55:02
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 06:17:08
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: C-section - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	01 Sep 2020 20:16:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Sep 2020 20:16:45
Data point term sent to Coder	System	01 Sep 2020 20:15:46
User entered 'C Section'	Madhu Balachandran (b) (4)	01 Sep 2020 20:15:26

US3542108

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '30 Jun 2008'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:15:26

US3542108

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:06:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:15:26

US3542108

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:06:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	29 Oct 2020 20:54:51
	(b) (4)	
User entered 'No (N)' reason for change: Per Query Resolution	David Diemert (b) (4)	29 Oct 2020 20:54:51
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	05 Sep 2020 21:37:17
	(b) (4)	
User entered 'Yes (Y)'	Madhu Balachandran	01 Sep 2020 20:15:26
	(b) (4)	

US3542108

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	29 Oct 2020 20:54:51
	(b) (4)	
User entered '30 Jun 2008' reason for change: Per Query Resolution	David Diemert (b) (4)	29 Oct 2020 20:54:51
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
	(b) (4)	
User entered empty.	Madhu Balachandran	01 Sep 2020 20:15:26
	(b) (4)	

US3542108

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:06:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:15:26

US3542108

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered 'Jun 2008'	System	01 Sep 2020 20:15:26

US3542108

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered '2008'	System	01 Sep 2020 20:15:26

US3542108

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered 'Jun 2008'	System	29 Oct 2020 20:54:51
User entered empty.	System	01 Sep 2020 20:15:26

US3542108

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered '2008'	System	29 Oct 2020 20:54:51
User entered empty.	System	01 Sep 2020 20:15:26

US3542108

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:06:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 07:19:25
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'Updated.' (Site from DM).	David Diemert (b) (4) (b) (4)	29 Oct 2020 20:57:10
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 06:18:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Mastectomies, PT: Mastectomy, LLT: Mastectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 13:10:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 13:10:35
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:37:17
Data point term sent to Coder	System	01 Sep 2020 20:19:58
User entered 'Mastectomy - Flap Reconstruction'	Madhu Balachandran (b) (4)	01 Sep 2020 20:19:29

US3542108

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'UN Apr 2017'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:19:29

US3542108

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:06:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:19:29

US3542108

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:06:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) David Diemert (b) (4)	03 Nov 2020 03:27:47 30 Oct 2020 01:19:07
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate.' answered with 'Updated.' (Site from DM). Signature has been broken.	David Diemert (b) (4) David Diemert (b) (4)	29 Oct 2020 20:57:38 29 Oct 2020 20:57:00
User entered 'No (N)' reason for change: Per Query Resolution	David Diemert (b) (4)	29 Oct 2020 20:57:00
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) David Diemert (b) (4)	05 Oct 2020 06:18:59 05 Sep 2020 21:37:17
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	01 Sep 2020 20:19:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Madhu Balachandran (b) (4)	01 Sep 2020 20:19:46
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	01 Sep 2020 20:19:29
User entered 'No (N)'	Madhu Balachandran (b) (4)	01 Sep 2020 20:19:29

US3542108

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	29 Oct 2020 20:57:00
	(b) (4)	
User entered 'un Apr 2017' reason for change: Data Entry Error	David Diemert (b) (4)	29 Oct 2020 20:57:00
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
	(b) (4)	
User entered empty.	Madhu Balachandran	01 Sep 2020 20:19:29
	(b) (4)	

US3542108

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:06:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:19:29

US3542108

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered 'Apr 2017'	System	01 Sep 2020 20:19:29

US3542108

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered '2017'	System	01 Sep 2020 20:19:29

US3542108

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered 'Apr 2017'	System	29 Oct 2020 20:57:00
User entered empty.	System	01 Sep 2020 20:19:29

US3542108

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered '2017'	System	29 Oct 2020 20:57:00
User entered empty.	System	01 Sep 2020 20:19:29

US3542108

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:06:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
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)	07 Oct 2020 17:30:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	07 Oct 2020 17:30:10
Data point term sent to Coder	System	07 Oct 2020 17:28:58
User entered 'Anxiety'	Hannah Yellin (b) (4)	07 Oct 2020 17:28:08
	(b) (4)	

US3542108

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered 'un UNK 2018'	(b) (4) Hannah Yellin (b) (4) (b) (4)	07 Oct 2020 17:28:08

US3542108

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:06:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	07 Oct 2020 17:28:08

US3542108

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:06:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	07 Oct 2020 17:28:08

US3542108

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	07 Oct 2020 17:28:08

US3542108

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:06:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	07 Oct 2020 17:28:08

US3542108

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered 'Jan 2018'	System	07 Oct 2020 17:28:08

US3542108

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered '2018'	System	07 Oct 2020 17:28:08

US3542108

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered empty.	System	07 Oct 2020 17:28:08

US3542108

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered empty.	System	07 Oct 2020 17:28:08

US3542108

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:06:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin and subcutaneous tissue therapeutic procedures NEC, PT: Dermal filler injection, LLT: Dermal filler injection - version MedDRA\\23.0.	Coder Import (b) (4)	28 Dec 2020 15:09:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	28 Dec 2020 15:09:20
Data point term sent to Coder	System	22 Dec 2020 22:02:42
User signature succeeded.	David Diemert (b) (4)	22 Dec 2020 22:02:38
User entered 'Dermal filler (Voluma) cheek injections, bilaterl'	David Diemert (b) (4)	22 Dec 2020 22:02:00

US3542108

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	22 Dec 2020 22:02:38
User entered 'UN Mar 2020'	(b) (4) David Diemert (b) (4) (b) (4)	22 Dec 2020 22:02:00

US3542108

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:06:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	22 Dec 2020 22:02:38
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	22 Dec 2020 22:02:00

US3542108

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:06:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	22 Dec 2020 22:02:38
User entered 'No (N)'	(b) (4) David Diemert (b) (4) (b) (4)	22 Dec 2020 22:02:00

US3542108

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	22 Dec 2020 22:02:38
User entered 'UN Mar 2020'	(b) (4) David Diemert (b) (4) (b) (4)	22 Dec 2020 22:02:00

US3542108

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:06:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	22 Dec 2020 22:02:38
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	22 Dec 2020 22:02:00

US3542108

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered 'Mar 2020'	System	22 Dec 2020 22:02:00

US3542108

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered '2020'	System	22 Dec 2020 22:02:00

US3542108

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered 'Mar 2020'	System	22 Dec 2020 22:02:00

US3542108

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered '2020'	System	22 Dec 2020 22:02:00

US3542108

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:24:38

US3542108

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '31 Aug 2020'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:24:38

US3542108

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '14:45'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:24:38

US3542108

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered '31 Aug 2020 14:45'	System	01 Sep 2020 20:24:38

US3542108

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '63' in	(b) (4) Madhu Balachandran	01 Sep 2020 20:24:38
DataPoint set to visible.	(b) (4) System	31 Aug 2020 18:30:38

US3542108

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '108' lb	(b) (4) Madhu Balachandran	01 Sep 2020 20:24:38
DataPoint set to visible.	(b) (4) System	31 Aug 2020 18:30:38

US3542108

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered '19.17134'	System	01 Sep 2020 20:24:38
DataPoint set to visible.	System	31 Aug 2020 18:30:38

US3542108

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered 'kg/m2'	System	01 Sep 2020 20:24:38
DataPoint set to visible.	System	31 Aug 2020 18:30:38

US3542108

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered missing code ND - Not Done.	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:24:38

US3542108

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:24:38

US3542108

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:24:38

US3542108

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered missing code ND - Not Done.	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:24:38

US3542108

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered 'bpm'	System	01 Sep 2020 20:24:38

US3542108

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered missing code ND - Not Done.	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:24:38

US3542108

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered 'breaths/min'	System	01 Sep 2020 20:24:38

US3542108

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered missing code ND - Not Done.	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:24:38

US3542108

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered 'mmHg'	System	01 Sep 2020 20:24:38

US3542108

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered missing code ND - Not Done.	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:24:38

US3542108

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered 'mmHg'	System	01 Sep 2020 20:24:38

US3542108

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26

US3542108

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26

US3542108

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:06:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 23:00:34
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	18 Dec 2020 20:14:07
User entered 'Yes (Y)' reason for change: New Information	(b) (4)	
	Erika Faust (b) (4)	18 Dec 2020 20:14:07
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
	(b) (4)	
User entered 'No (N)'	Madhu Balachandran	01 Sep 2020 20:24:43
	(b) (4)	

US3542108

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:06:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 23:00:34
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	18 Dec 2020 20:14:07
User entered '31 Aug 2020' reason for change: New Information	(b) (4)	
	Erika Faust (b) (4)	18 Dec 2020 20:14:07
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered empty.	(b) (4)	
	Madhu Balachandran	01 Sep 2020 20:24:43
	(b) (4)	

US3542108

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:06:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '31 Aug 2020'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:27:52

US3542108

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:27:52

US3542108

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'Partner medically sterile (PARTNER STERILE)'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:27:52

US3542108

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'Not indicated'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:27:52

US3542108

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:27:52

US3542108

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:06:32

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:27:52

US3542108

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:27:52

US3542108

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:06:32

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:27:52

US3542108

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:29:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:29:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:29:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:29:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:29:52

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:29:52

US3542108

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:29:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:29:52

US3542108

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:29:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:29:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:29:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:32

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:29:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:32

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:24:45
Signature has been broken.	(b) (4)	
	Hannah Yellin (b) (4)	15 Sep 2020 20:34:25
	(b) (4)	
User entered 'DIRECTOR OF (b) (6)	Hannah Yellin (b) (4)	15 Sep 2020 20:34:25
(b) (6)' reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
	(b) (4)	
User entered 'Directory of (b) (6) '	Madhu Balachandran	01 Sep 2020 20:29:52
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'l'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:29:52

US3542108

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:29:52

US3542108

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:29:52

US3542108

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:29:52

US3542108

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:29:52

US3542108

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:29:52

US3542108

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:32

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:29:52

US3542108

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:32

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:29:52

US3542108

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:06:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'Yes (Y)'	(b) (4) Elissa Malkin (b) (4)	31 Aug 2020 19:38:45

US3542108

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:06:32

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '31 Aug 2020'	Elissa Malkin (b) (4)	31 Aug 2020 19:38:45

US3542108

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:06:32

[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 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'Clinic (Clinic)'	Elissa Malkin (b) (4)	31 Aug 2020 19:38:45

US3542108

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:06:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered 'VISIT1'	System	31 Aug 2020 19:38:45

US3542108

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4)	05 Sep 2020 21:37:17
User entered '31 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 18:29:46

US3542108

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:37:17
User entered '110309'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 18:29:46

US3542108

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 18:29:46

US3542108

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:06:32

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 07:09:50
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:37:17
User entered 'No (N)'	Madhu Balachandran (b) (4)	01 Sep 2020 20:32:55

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:06:32

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 07:09:50
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:37:17
User entered 'No (N)'	Madhu Balachandran (b) (4)	01 Sep 2020 20:32:55

US3542108

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:32:55

US3542108

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:06:32

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:37:17
User entered 'No (N)'	Madhu Balachandran (b) (4)	01 Sep 2020 20:32:55

US3542108

Folder: Visit 1 Day 1

Form: Randomization

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[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:32:55

US3542108

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 02:53:34
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	15 Oct 2020 14:53:12
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 08:47:46
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:47:45

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:06:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered missing code ND - Not Done.	Madhu Balachandran (b) (4)	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:06:32

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered missing code ND - Not Done.	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:06:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered missing code ND - Not Done.	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:06:32

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered missing code ND - Not Done.	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User accepted default value 'Pre-Dose (PREDOSE)'	Madhu Balachandran (b) (4)	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	01 Sep 2020 20:34:51

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '31 Aug 2020'	Madhu Balachandran (b) (4)	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '14:45'	Madhu Balachandran (b) (4)	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered '31 Aug 2020 14:45'	System	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:37:17
User entered '98.1' F	Madhu Balachandran (b) (4)	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'Oral (Oral)'	Madhu Balachandran (b) (4)	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered empty.	Madhu Balachandran (b) (4)	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '73'	Madhu Balachandran (b) (4)	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered 'bpm'	System	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:37:17
User entered '16'	Madhu Balachandran (b) (4)	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered 'breaths/min'	System	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:37:17
User entered '123'	Madhu Balachandran (b) (4)	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered 'mmHg'	System	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:37:17
User entered '86'	Madhu Balachandran (b) (4)	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered 'mmHg'	System	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:06:32

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered missing code ND - Not Done.	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:06:32

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered missing code ND - Not Done.	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User accepted default value 'Post-Dose (POSTDOSE)'	Madhu Balachandran (b) (4)	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '31 Aug 2020'	Madhu Balachandran (b) (4)	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '16:05'	Madhu Balachandran (b) (4)	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered '31 Aug 2020 16:05'	System	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:37:17
User entered '97.8' F	Madhu Balachandran (b) (4)	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'Oral (Oral)'	Madhu Balachandran (b) (4)	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered empty.	Madhu Balachandran (b) (4)	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:37:17
User entered '69'	Madhu Balachandran (b) (4)	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered 'bpm'	System	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:37:17
User entered '16'	Madhu Balachandran (b) (4)	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered 'breaths/min'	System	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:37:17
User entered '148'	Madhu Balachandran (b) (4)	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered 'mmHg'	System	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:37:17
User entered '79'	Madhu Balachandran (b) (4)	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered 'mmHg'	System	01 Sep 2020 20:34:51

US3542108

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:06:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 23:00:34
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	18 Dec 2020 20:14:29
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Erika Faust (b) (4)	18 Dec 2020 20:14:29
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'Yes (Y)'	(b) (4)	
	Madhu Balachandran	01 Sep 2020 20:34:55
	(b) (4)	

US3542108

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:06:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 23:00:34
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	18 Dec 2020 20:14:29
User entered empty; reason for change New Information	(b) (4)	
	Erika Faust (b) (4)	18 Dec 2020 20:14:29
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	05 Sep 2020 21:37:17
	(b) (4)	
User closed query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	01 Sep 2020 20:35:04
User entered '31 Aug 2020' reason for change: Data Entry Error	Madhu Balachandran (b) (4)	01 Sep 2020 20:35:04
User opened query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	01 Sep 2020 20:34:55
User entered empty.	Madhu Balachandran (b) (4)	01 Sep 2020 20:34:55

US3542108

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'Yes (Y)'	(b) (4) Elissa Malkin (b) (4)	31 Aug 2020 19:39:06

US3542108

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:32

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered empty.	(b) (4) Elissa Malkin (b) (4)	31 Aug 2020 19:39:06

US3542108

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:32

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 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered empty.	(b) (4) Elissa Malkin (b) (4)	31 Aug 2020 19:39:06

US3542108

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:32

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered 'MRNA-1273 OR PLACEBO'	System	31 Aug 2020 19:39:06

US3542108

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '31 Aug 2020'	(b) (4) Elissa Malkin (b) (4)	31 Aug 2020 19:39:06

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '15:30'	(b) (4) Elissa Malkin (b) (4)	31 Aug 2020 19:39:06

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered '31 Aug 2020 15:30'	System	31 Aug 2020 19:39:06

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'Left Arm (LEFT ARM)'	Elissa Malkin (b) (4)	31 Aug 2020 19:39:06

US3542108

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered 'ONCE'	System	31 Aug 2020 19:39:06

US3542108

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:32

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered 'INTRAMUSCULAR'	System	31 Aug 2020 19:39:06

US3542108

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	01 Sep 2020 20:35:42

US3542108

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '31 Aug 2020'	Madhu Balachandran (b) (4)	01 Sep 2020 20:35:42

US3542108

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '14:45'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:35:42

US3542108

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered '31 Aug 2020 14:45'	System	01 Sep 2020 20:35:42

US3542108

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:06:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '31 Aug 2020'	Madhu Balachandran (b) (4)	01 Sep 2020 20:35:54

US3542108

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:06:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Madhu Balachandran (b) (4)	01 Sep 2020 20:35:54

US3542108

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:06:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	01 Sep 2020 20:35:54

US3542108

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:06:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 21:37:17
User entered '14:50'	Madhu Balachandran (b) (4)	01 Sep 2020 20:35:54

US3542108

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered '31 Aug 2020 14:50'	System	01 Sep 2020 20:35:54

US3542108

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:06:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Madhu Balachandran (b) (4)	01 Sep 2020 20:35:54

US3542108

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:06:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'No (N)'	Madhu Balachandran (b) (4)	01 Sep 2020 20:35:54

US3542108

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:06:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered empty.	Madhu Balachandran (b) (4)	01 Sep 2020 20:35:54

US3542108

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered empty.	System	01 Sep 2020 20:35:54

US3542108

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	01 Sep 2020 20:35:57

US3542108

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:06:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered 'I'	System	01 Sep 2020 20:35:57

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	31 Aug 2020 19:39:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-08-31T16:07:33', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'da9a67bf-05db-4925-8f50-3aedc52eff97' User entered 'Yes (Y)'	System	31 Aug 2020 20:07:56
	System	31 Aug 2020 20:07:56

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-08-31T16:07:39', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'da9a67bf-05db-4925-8f50-3aedc52eff97' User entered '97.8'	System	31 Aug 2020 20:07:56
	System	31 Aug 2020 20:07:56

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-08-31T16:07:44', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'da9a67bf-05db-4925-8f50-3aedc52eff97'	System	31 Aug 2020 20:07:56
User entered 'No (N)'	System	31 Aug 2020 20:07:56

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-08-31T16:07:50', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'da9a67bf-05db-4925-8f50-3aedc52eff97'	System	31 Aug 2020 20:07:56
User entered '31 Aug 2020 16:07'	System	31 Aug 2020 20:07:56

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '31 Aug 2020 15:50'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '31 Aug 2020 18:20'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	31 Aug 2020 19:39:06
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-08-31T19:34:24', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '6cd0b9b2-9c63-4b4e-8218-36b0b6a824b8' User entered 'Yes (Y)'	System	31 Aug 2020 23:34:46
	System	31 Aug 2020 23:34:46

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-08-31T19:34:27', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '6cd0b9b2-9c63-4b4e-8218-36b0b6a824b8' User entered '97.5'	System	31 Aug 2020 23:34:46
	System	31 Aug 2020 23:34:46

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-08-31T19:34:31', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '6cd0b9b2-9c63-4b4e-8218-36b0b6a824b8'	System	31 Aug 2020 23:34:46
User entered 'No (N)'	System	31 Aug 2020 23:34:46

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-08-31T19:34:36', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '6cd0b9b2-9c63-4b4e-8218-36b0b6a824b8' User entered '31 Aug 2020 19:34'	System	31 Aug 2020 23:34:46
	System	31 Aug 2020 23:34:46

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '31 Aug 2020 19:15'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	31 Aug 2020 19:39:06
User entered 'Day 2'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:06:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-01T21:32:21', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'edf8408d-de3f-46dc-8ad9-688ca5112c83'	System	02 Sep 2020 01:32:38
User entered 'Yes (Y)'	System	02 Sep 2020 01:32:38

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:06:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-01T21:32:26', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'edf8408d-de3f-46dc-8ad9-688ca5112c83' User entered '97.7'	System	02 Sep 2020 01:32:38
	System	02 Sep 2020 01:32:38

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-01T21:32:30', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'edf8408d-de3f-46dc-8ad9-688ca5112c83'	System	02 Sep 2020 01:32:38
User entered 'No (N)'	System	02 Sep 2020 01:32:38

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:06:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-01T21:32:35', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'edf8408d-de3f-46dc-8ad9-688ca5112c83' User entered '01 Sep 2020 21:32'	System	02 Sep 2020 01:32:38
	System	02 Sep 2020 01:32:38

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	31 Aug 2020 19:39:06
User entered 'Day 3'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:06:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-02T19:14:15', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'ed83a2cc-d665-4f97-805a-3679422ff2c2'	System	02 Sep 2020 23:14:30
User entered 'Yes (Y)'	System	02 Sep 2020 23:14:30

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:06:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-02T19:14:19', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'ed83a2cc-d665-4f97-805a-3679422ff2c2' User entered '97.7'	System	02 Sep 2020 23:14:30
	System	02 Sep 2020 23:14:30

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-02T19:14:22', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'ed83a2cc-d665-4f97-805a-3679422ff2c2'	System	02 Sep 2020 23:14:30
User entered 'No (N)'	System	02 Sep 2020 23:14:30

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:06:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-02T19:14:27', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'ed83a2cc-d665-4f97-805a-3679422ff2c2'	System	02 Sep 2020 23:14:30
User entered '02 Sep 2020 19:14'	System	02 Sep 2020 23:14:30

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	31 Aug 2020 19:39:06
User entered 'Day 4'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:06:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-03T21:31:03', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '6596e82a-8576-4ab8-b0b8-49616f86861d' User entered 'Yes (Y)'	System	04 Sep 2020 01:31:19
	System	04 Sep 2020 01:31:19

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:06:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-03T21:31:07', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '6596e82a-8576-4ab8-b0b8-49616f86861d' User entered '97.3'	System	04 Sep 2020 01:31:19
	System	04 Sep 2020 01:31:19

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-03T21:31:10', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '6596e82a-8576-4ab8-b0b8-49616f86861d' User entered 'No (N)'	System	04 Sep 2020 01:31:19
	System	04 Sep 2020 01:31:19

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:06:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-03T21:31:15', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '6596e82a-8576-4ab8-b0b8-49616f86861d' User entered '03 Sep 2020 21:31'	System	04 Sep 2020 01:31:19
	System	04 Sep 2020 01:31:19

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	31 Aug 2020 19:39:06
User entered 'Day 5'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:06:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-04T23:53:17', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '14591e78-e264-47f5-a0be-3ea44d791ad5' User entered 'Yes (Y)'	System	05 Sep 2020 03:53:34
	System	05 Sep 2020 03:53:34

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:06:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-04T23:53:21', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '14591e78-e264-47f5-a0be-3ea44d791ad5' User entered '97.8'	System	05 Sep 2020 03:53:34
	System	05 Sep 2020 03:53:34

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-04T23:53:23', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '14591e78-e264-47f5-a0be-3ea44d791ad5'	System	05 Sep 2020 03:53:34
User entered 'No (N)'	System	05 Sep 2020 03:53:34

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:06:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-04T23:53:30', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '14591e78-e264-47f5-a0be-3ea44d791ad5' User entered '04 Sep 2020 23:53'	System	05 Sep 2020 03:53:34
	System	05 Sep 2020 03:53:34

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	31 Aug 2020 19:39:06
User entered 'Day 6'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:06:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-05T20:16:37', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'fecba435-7217-4c62-828b-09e3ff7bee7c' User entered 'Yes (Y)'	System	06 Sep 2020 00:16:55
	System	06 Sep 2020 00:16:55

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:06:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-05T20:16:42', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'fecba435-7217-4c62-828b-09e3ff7bee7c' User entered '97.8'	System	06 Sep 2020 00:16:55
	System	06 Sep 2020 00:16:55

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-05T20:16:46', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'fecba435-7217-4c62-828b-09e3ff7bee7c'	System	06 Sep 2020 00:16:55
User entered 'No (N)'	System	06 Sep 2020 00:16:55

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:06:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-05T20:16:50', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'fecba435-7217-4c62-828b-09e3ff7bee7c' User entered '05 Sep 2020 20:16'	System	06 Sep 2020 00:16:55
	System	06 Sep 2020 00:16:55

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	31 Aug 2020 19:39:06
User entered 'Day 7'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:06:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-06T21:54:25', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'c00d232a-d401-444e-b7de-25b0a35f1560' User entered 'Yes (Y)'	System	07 Sep 2020 01:54:40
	System	07 Sep 2020 01:54:40

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:06:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-06T21:54:30', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'c00d232a-d401-444e-b7de-25b0a35f1560' User entered '97.3'	System	07 Sep 2020 01:54:40
	System	07 Sep 2020 01:54:40

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-06T21:54:32', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'c00d232a-d401-444e-b7de-25b0a35f1560' User entered 'No (N)'	System	07 Sep 2020 01:54:40
	System	07 Sep 2020 01:54:40

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:06:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-06T21:54:39', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'c00d232a-d401-444e-b7de-25b0a35f1560' User entered '06 Sep 2020 21:54'	System	07 Sep 2020 01:54:40
	System	07 Sep 2020 01:54:40

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	31 Aug 2020 19:39:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-08-31T16:07:57', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'c355f416-6e1b-4cb9-bf59-97a2e3d2dd98'	System	31 Aug 2020 20:08:15
User entered 'None (1)'	System	31 Aug 2020 20:08:15

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-08-31T16:08:02', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'c355f416-6e1b-4cb9-bf59-97a2e3d2dd98'	System	31 Aug 2020 20:08:15
User entered 'No (N)'	System	31 Aug 2020 20:08:15

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-08-31T16:08:07', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'c355f416-6e1b-4cb9-bf59-97a2e3d2dd98'	System	31 Aug 2020 20:08:15
User entered 'No (N)'	System	31 Aug 2020 20:08:15

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-08-31T16:08:10', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'c355f416-6e1b-4cb9-bf59-97a2e3d2dd98'	System	31 Aug 2020 20:08:15
User entered 'None (1)'	System	31 Aug 2020 20:08:15

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-08-31T16:08:13', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'c355f416-6e1b-4cb9-bf59-97a2e3d2dd98'	System	31 Aug 2020 20:08:15
User entered '31 Aug 2020 16:08'	System	31 Aug 2020 20:08:15

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '31 Aug 2020 15:50'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '31 Aug 2020 18:20'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	31 Aug 2020 19:39:06
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-08-31T19:35:23', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'b89a4c7f-2629-4b79-86e1-2d8e20100323' User entered 'None (1)'	System	31 Aug 2020 23:35:46
	System	31 Aug 2020 23:35:46

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-08-31T19:35:26', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'b89a4c7f-2629-4b79-86e1-2d8e20100323' User entered 'No (N)'	System	31 Aug 2020 23:35:46
	System	31 Aug 2020 23:35:46

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-08-31T19:35:32', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'b89a4c7f-2629-4b79-86e1-2d8e20100323' User entered 'No (N)'	System	31 Aug 2020 23:35:46
	System	31 Aug 2020 23:35:46

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-08-31T19:35:36', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'b89a4c7f-2629-4b79-86e1-2d8e20100323' User entered 'None (1)'	System	31 Aug 2020 23:35:46
	System	31 Aug 2020 23:35:46

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-08-31T19:35:43', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'b89a4c7f-2629-4b79-86e1-2d8e20100323' User entered '31 Aug 2020 19:35'	System	31 Aug 2020 23:35:46
	System	31 Aug 2020 23:35:46

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '31 Aug 2020 19:15'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	31 Aug 2020 19:39:06
User entered 'Day 2'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-01T21:33:03', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'df3b8650-bea2-4364-bfb1-abc689eef659'	System	02 Sep 2020 01:33:55
User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 01:33:55

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-01T21:33:33', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'df3b8650-bea2-4364-bfb1-abc689eef659'	System	02 Sep 2020 01:33:55
User entered 'No (N)'	System	02 Sep 2020 01:33:55

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-01T21:33:41', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'df3b8650-bea2-4364-bfb1-abc689eef659'	System	02 Sep 2020 01:33:55
User entered 'No (N)'	System	02 Sep 2020 01:33:55

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-01T21:33:47', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'df3b8650-bea2-4364-bfb1-abc689eef659'	System	02 Sep 2020 01:33:55
User entered 'None (1)'	System	02 Sep 2020 01:33:55

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-01T21:33:53', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'df3b8650-bea2-4364-bfb1-abc689eef659' User entered '01 Sep 2020 21:33'	System	02 Sep 2020 01:33:55
	System	02 Sep 2020 01:33:55

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	31 Aug 2020 19:39:06
User entered 'Day 3'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-02T19:14:31', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '61335039-f767-41ee-aaad-cf4c9da2f3f9'	System	02 Sep 2020 23:14:48
User entered 'None (1)'	System	02 Sep 2020 23:14:48

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-02T19:14:34', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '61335039-f767-41ee-aaad-cf4c9da2f3f9'	System	02 Sep 2020 23:14:48
User entered 'No (N)'	System	02 Sep 2020 23:14:48

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-02T19:14:39', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '61335039-f767-41ee-aaad-cf4c9da2f3f9'	System	02 Sep 2020 23:14:48
User entered 'No (N)'	System	02 Sep 2020 23:14:48

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-02T19:14:43', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '61335039-f767-41ee-aaad-cf4c9da2f3f9'	System	02 Sep 2020 23:14:48
User entered 'None (1)'	System	02 Sep 2020 23:14:48

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-02T19:14:45', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '61335039-f767-41ee-aaad-cf4c9da2f3f9'	System	02 Sep 2020 23:14:48
User entered '02 Sep 2020 19:14'	System	02 Sep 2020 23:14:48

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	31 Aug 2020 19:39:06
User entered 'Day 4'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-03T21:31:54', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'c6bc8456-ac74-4e7d-a9ba-0f814a1d4fe1' User entered 'None (1)'	System	04 Sep 2020 01:32:12
	System	04 Sep 2020 01:32:12

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-03T21:32:02', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'c6bc8456-ac74-4e7d-a9ba-0f814a1d4fe1' User entered 'No (N)'	System	04 Sep 2020 01:32:12
	System	04 Sep 2020 01:32:12

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-03T21:32:04', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'c6bc8456-ac74-4e7d-a9ba-0f814a1d4fe1' User entered 'No (N)'	System	04 Sep 2020 01:32:12
	System	04 Sep 2020 01:32:12

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-03T21:32:07', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'c6bc8456-ac74-4e7d-a9ba-0f814a1d4fe1'	System	04 Sep 2020 01:32:12
User entered 'None (1)'	System	04 Sep 2020 01:32:12

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-03T21:32:10', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'c6bc8456-ac74-4e7d-a9ba-0f814a1d4fe1' User entered '03 Sep 2020 21:32'	System	04 Sep 2020 01:32:12
	System	04 Sep 2020 01:32:12

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	31 Aug 2020 19:39:06
User entered 'Day 5'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-04T23:53:37', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '2fd9e536-5c7e-4de7-ad73-8d470b0c2b5e' User entered 'None (1)'	System	05 Sep 2020 03:53:55
	System	05 Sep 2020 03:53:55

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-04T23:53:40', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '2fd9e536-5c7e-4de7-ad73-8d470b0c2b5e' User entered 'No (N)'	System	05 Sep 2020 03:53:55
	System	05 Sep 2020 03:53:55

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-04T23:53:46', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '2fd9e536-5c7e-4de7-ad73-8d470b0c2b5e' User entered 'No (N)'	System	05 Sep 2020 03:53:55
	System	05 Sep 2020 03:53:55

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-04T23:53:51', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '2fd9e536-5c7e-4de7-ad73-8d470b0c2b5e' User entered 'None (1)'	System	05 Sep 2020 03:53:55
	System	05 Sep 2020 03:53:55

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-04T23:53:54', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '2fd9e536-5c7e-4de7-ad73-8d470b0c2b5e' User entered '04 Sep 2020 23:53'	System	05 Sep 2020 03:53:55
	System	05 Sep 2020 03:53:55

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	31 Aug 2020 19:39:06
User entered 'Day 6'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-05T20:16:57', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'e1150e73-46bb-47bd-97f8-321a42b7e6da' User entered 'None (1)'	System	06 Sep 2020 00:17:40
	System	06 Sep 2020 00:17:40

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-05T20:17:04', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'e1150e73-46bb-47bd-97f8-321a42b7e6da' User entered 'No (N)'	System	06 Sep 2020 00:17:40
	System	06 Sep 2020 00:17:40

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-05T20:17:13', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'e1150e73-46bb-47bd-97f8-321a42b7e6da' User entered 'No (N)'	System	06 Sep 2020 00:17:40
	System	06 Sep 2020 00:17:40

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-05T20:17:16', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'e1150e73-46bb-47bd-97f8-321a42b7e6da' User entered 'None (1)'	System	06 Sep 2020 00:17:40
	System	06 Sep 2020 00:17:40

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-05T20:17:39', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'e1150e73-46bb-47bd-97f8-321a42b7e6da' User entered '05 Sep 2020 20:17'	System	06 Sep 2020 00:17:40
	System	06 Sep 2020 00:17:40

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	31 Aug 2020 19:39:06
User entered 'Day 7'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-06T21:54:44', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '1146ed14-4b82-41aa-9ca3-56b630fc0fe5' User entered 'None (1)'	System	07 Sep 2020 01:55:05
	System	07 Sep 2020 01:55:05

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-06T21:54:47', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '1146ed14-4b82-41aa-9ca3-56b630fc0fe5' User entered 'No (N)'	System	07 Sep 2020 01:55:05
	System	07 Sep 2020 01:55:05

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-06T21:54:51', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '1146ed14-4b82-41aa-9ca3-56b630fc0fe5' User entered 'No (N)'	System	07 Sep 2020 01:55:05
	System	07 Sep 2020 01:55:05

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-06T21:54:58', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '1146ed14-4b82-41aa-9ca3-56b630fc0fe5' User entered 'None (1)'	System	07 Sep 2020 01:55:05
	System	07 Sep 2020 01:55:05

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-06T21:55:03', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '1146ed14-4b82-41aa-9ca3-56b630fc0fe5' User entered '06 Sep 2020 21:55'	System	07 Sep 2020 01:55:05
	System	07 Sep 2020 01:55:05

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	31 Aug 2020 19:39:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-08-31T16:08:18', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '4eb01520-06b4-4844-a32d-d1bd7b840239' User entered 'None (0)'	System	31 Aug 2020 20:08:43
	System	31 Aug 2020 20:08:43

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-08-31T16:08:19', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '4eb01520-06b4-4844-a32d-d1bd7b840239' User entered 'None (0)'	System	31 Aug 2020 20:08:43
	System	31 Aug 2020 20:08:43

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-08-31T16:08:23', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '4eb01520-06b4-4844-a32d-d1bd7b840239' User entered 'None (0)'	System	31 Aug 2020 20:08:43
	System	31 Aug 2020 20:08:43

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-08-31T16:08:25', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '4eb01520-06b4-4844-a32d-d1bd7b840239' User entered 'None (0)'	System	31 Aug 2020 20:08:43
	System	31 Aug 2020 20:08:43

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-08-31T16:08:27', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '4eb01520-06b4-4844-a32d-d1bd7b840239' User entered 'None (0)'	System	31 Aug 2020 20:08:43
	System	31 Aug 2020 20:08:43

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-08-31T16:08:29', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '4eb01520-06b4-4844-a32d-d1bd7b840239' User entered 'None (0)'	System	31 Aug 2020 20:08:43
	System	31 Aug 2020 20:08:43

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-08-31T16:08:34', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '4eb01520-06b4-4844-a32d-d1bd7b840239'	System	31 Aug 2020 20:08:43
User entered 'No (N)'	System	31 Aug 2020 20:08:43

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-08-31T16:08:37', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '4eb01520-06b4-4844-a32d-d1bd7b840239' User entered '31 Aug 2020 16:08'	System	31 Aug 2020 20:08:43
	System	31 Aug 2020 20:08:43

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '31 Aug 2020 15:50'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '31 Aug 2020 18:20'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	31 Aug 2020 19:39:06
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-08-31T19:34:53', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '0798dc9b-c108-486f-aba0-907e7cfafaa0' User entered 'None (0)'	System	31 Aug 2020 23:35:20
	System	31 Aug 2020 23:35:20

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-08-31T19:35:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '0798dc9b-c108-486f-aba0-907e7cfafaa0' User entered 'None (0)'	System	31 Aug 2020 23:35:20
	System	31 Aug 2020 23:35:20

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-08-31T19:35:03', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '0798dc9b-c108-486f-aba0-907e7cfafaa0' User entered 'None (0)'	System	31 Aug 2020 23:35:20
	System	31 Aug 2020 23:35:20

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-08-31T19:35:05', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '0798dc9b-c108-486f-aba0-907e7cfafaa0' User entered 'None (0)'	System	31 Aug 2020 23:35:20
	System	31 Aug 2020 23:35:20

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-08-31T19:35:07', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '0798dc9b-c108-486f-aba0-907e7cfafaa0' User entered 'None (0)'	System	31 Aug 2020 23:35:20
	System	31 Aug 2020 23:35:20

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-08-31T19:35:09', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '0798dc9b-c108-486f-aba0-907e7cfafaa0' User entered 'None (0)'	System	31 Aug 2020 23:35:20
	System	31 Aug 2020 23:35:20

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-08-31T19:35:11', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '0798dc9b-c108-486f-aba0-907e7cfafaa0' User entered 'No (N)'	System	31 Aug 2020 23:35:20
	System	31 Aug 2020 23:35:20

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-08-31T19:35:17', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '0798dc9b-c108-486f-aba0-907e7cfafaa0' User entered '31 Aug 2020 19:35'	System	31 Aug 2020 23:35:20
	System	31 Aug 2020 23:35:20

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '31 Aug 2020 19:15'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	31 Aug 2020 19:39:06
User entered 'Day 2'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-01T21:33:59', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '4b9d5118-0026-48ee-a542-5348921a6a46' User entered 'None (0)'	System	02 Sep 2020 01:34:31
	System	02 Sep 2020 01:34:31

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-01T21:34:08', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '4b9d5118-0026-48ee-a542-5348921a6a46' User entered 'None (0)'	System	02 Sep 2020 01:34:31
	System	02 Sep 2020 01:34:31

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-01T21:34:11', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '4b9d5118-0026-48ee-a542-5348921a6a46' User entered 'None (0)'	System	02 Sep 2020 01:34:31
	System	02 Sep 2020 01:34:31

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-01T21:34:14', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '4b9d5118-0026-48ee-a542-5348921a6a46' User entered 'None (0)'	System	02 Sep 2020 01:34:31
	System	02 Sep 2020 01:34:31

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-01T21:34:16', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '4b9d5118-0026-48ee-a542-5348921a6a46' User entered 'None (0)'	System	02 Sep 2020 01:34:31
	System	02 Sep 2020 01:34:31

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-01T21:34:18', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '4b9d5118-0026-48ee-a542-5348921a6a46' User entered 'None (0)'	System	02 Sep 2020 01:34:31
	System	02 Sep 2020 01:34:31

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-01T21:34:23', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '4b9d5118-0026-48ee-a542-5348921a6a46' User entered 'No (N)'	System	02 Sep 2020 01:34:31
	System	02 Sep 2020 01:34:31

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-01T21:34:29', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '4b9d5118-0026-48ee-a542-5348921a6a46' User entered '01 Sep 2020 21:34'	System	02 Sep 2020 01:34:31
	System	02 Sep 2020 01:34:31

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	31 Aug 2020 19:39:06
User entered 'Day 3'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-02T19:14:49', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'a56be323-399e-459b-9648-18691824ce05' User entered 'None (0)'	System	02 Sep 2020 23:15:07
	System	02 Sep 2020 23:15:07

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-02T19:14:51', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'a56be323-399e-459b-9648-18691824ce05' User entered 'None (0)'	System	02 Sep 2020 23:15:07
	System	02 Sep 2020 23:15:07

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-02T19:14:53', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'a56be323-399e-459b-9648-18691824ce05' User entered 'None (0)'	System	02 Sep 2020 23:15:07
	System	02 Sep 2020 23:15:07

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-02T19:14:55', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'a56be323-399e-459b-9648-18691824ce05' User entered 'None (0)'	System	02 Sep 2020 23:15:07
	System	02 Sep 2020 23:15:07

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-02T19:14:57', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'a56be323-399e-459b-9648-18691824ce05' User entered 'None (0)'	System	02 Sep 2020 23:15:07
	System	02 Sep 2020 23:15:07

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-02T19:14:59', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'a56be323-399e-459b-9648-18691824ce05' User entered 'None (0)'	System	02 Sep 2020 23:15:07
	System	02 Sep 2020 23:15:07

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-02T19:15:02', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'a56be323-399e-459b-9648-18691824ce05' User entered 'No (N)'	System	02 Sep 2020 23:15:07
	System	02 Sep 2020 23:15:07

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-02T19:15:05', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'a56be323-399e-459b-9648-18691824ce05' User entered '02 Sep 2020 19:15'	System	02 Sep 2020 23:15:07
	System	02 Sep 2020 23:15:07

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	31 Aug 2020 19:39:06
User entered 'Day 4'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-03T21:32:22', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '9e7949a3-10ef-4481-98d0-66a10267dc31' User entered 'None (0)'	System	04 Sep 2020 01:32:46
	System	04 Sep 2020 01:32:46

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-03T21:32:25', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '9e7949a3-10ef-4481-98d0-66a10267dc31' User entered 'None (0)'	System	04 Sep 2020 01:32:46
	System	04 Sep 2020 01:32:46

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-03T21:32:27', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '9e7949a3-10ef-4481-98d0-66a10267dc31' User entered 'None (0)'	System	04 Sep 2020 01:32:46
	System	04 Sep 2020 01:32:46

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-03T21:32:29', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '9e7949a3-10ef-4481-98d0-66a10267dc31' User entered 'None (0)'	System	04 Sep 2020 01:32:46
	System	04 Sep 2020 01:32:46

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-03T21:32:31', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '9e7949a3-10ef-4481-98d0-66a10267dc31' User entered 'None (0)'	System	04 Sep 2020 01:32:46
	System	04 Sep 2020 01:32:46

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-03T21:32:33', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '9e7949a3-10ef-4481-98d0-66a10267dc31' User entered 'None (0)'	System	04 Sep 2020 01:32:46
	System	04 Sep 2020 01:32:46

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-03T21:32:38', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '9e7949a3-10ef-4481-98d0-66a10267dc31' User entered 'No (N)'	System	04 Sep 2020 01:32:46
	System	04 Sep 2020 01:32:46

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-03T21:32:40', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '9e7949a3-10ef-4481-98d0-66a10267dc31' User entered '03 Sep 2020 21:32'	System	04 Sep 2020 01:32:46
	System	04 Sep 2020 01:32:46

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	31 Aug 2020 19:39:06
User entered 'Day 5'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-04T23:53:58', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '205e7e68-643e-49b2-a934-2f11271f2e99'	System	05 Sep 2020 03:54:17
User entered 'None (0)'	System	05 Sep 2020 03:54:17

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-04T23:54:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '205e7e68-643e-49b2-a934-2f11271f2e99' User entered 'None (0)'	System	05 Sep 2020 03:54:17
	System	05 Sep 2020 03:54:17

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-04T23:54:02', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '205e7e68-643e-49b2-a934-2f11271f2e99' User entered 'None (0)'	System	05 Sep 2020 03:54:17
	System	05 Sep 2020 03:54:17

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-04T23:54:04', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '205e7e68-643e-49b2-a934-2f11271f2e99' User entered 'None (0)'	System	05 Sep 2020 03:54:17
	System	05 Sep 2020 03:54:17

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-04T23:54:07', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '205e7e68-643e-49b2-a934-2f11271f2e99' User entered 'None (0)'	System	05 Sep 2020 03:54:17
	System	05 Sep 2020 03:54:17

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-04T23:54:09', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '205e7e68-643e-49b2-a934-2f11271f2e99' User entered 'None (0)'	System	05 Sep 2020 03:54:17
	System	05 Sep 2020 03:54:17

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-04T23:54:13', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '205e7e68-643e-49b2-a934-2f11271f2e99'	System	05 Sep 2020 03:54:17
User entered 'No (N)'	System	05 Sep 2020 03:54:17

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-04T23:54:15', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '205e7e68-643e-49b2-a934-2f11271f2e99'	System	05 Sep 2020 03:54:17
User entered '04 Sep 2020 23:54'	System	05 Sep 2020 03:54:17

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	31 Aug 2020 19:39:06
User entered 'Day 6'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-05T20:17:43', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '21422515-d27e-46a1-8aba-544bb18e6e01' User entered 'None (0)'	System	06 Sep 2020 00:18:08
	System	06 Sep 2020 00:18:08

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-05T20:17:45', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '21422515-d27e-46a1-8aba-544bb18e6e01' User entered 'None (0)'	System	06 Sep 2020 00:18:08
	System	06 Sep 2020 00:18:08

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-05T20:17:48', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '21422515-d27e-46a1-8aba-544bb18e6e01' User entered 'None (0)'	System	06 Sep 2020 00:18:08
	System	06 Sep 2020 00:18:08

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-05T20:17:50', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '21422515-d27e-46a1-8aba-544bb18e6e01' User entered 'None (0)'	System	06 Sep 2020 00:18:08
	System	06 Sep 2020 00:18:08

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-05T20:17:52', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '21422515-d27e-46a1-8aba-544bb18e6e01' User entered 'None (0)'	System	06 Sep 2020 00:18:08
	System	06 Sep 2020 00:18:08

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-05T20:17:53', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '21422515-d27e-46a1-8aba-544bb18e6e01' User entered 'None (0)'	System	06 Sep 2020 00:18:08
	System	06 Sep 2020 00:18:08

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-05T20:17:59', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '21422515-d27e-46a1-8aba-544bb18e6e01' User entered 'No (N)'	System	06 Sep 2020 00:18:08
	System	06 Sep 2020 00:18:08

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-05T20:18:05', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '21422515-d27e-46a1-8aba-544bb18e6e01' User entered '05 Sep 2020 20:18'	System	06 Sep 2020 00:18:08
	System	06 Sep 2020 00:18:08

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	31 Aug 2020 19:39:06
User entered 'Day 7'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-06T21:55:08', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '9c467764-8e9d-4f19-a3f3-49aa0e8040d8' User entered 'None (0)'	System	07 Sep 2020 01:55:25
	System	07 Sep 2020 01:55:25

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-06T21:55:09', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '9c467764-8e9d-4f19-a3f3-49aa0e8040d8' User entered 'None (0)'	System	07 Sep 2020 01:55:25
	System	07 Sep 2020 01:55:25

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-06T21:55:11', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '9c467764-8e9d-4f19-a3f3-49aa0e8040d8' User entered 'None (0)'	System	07 Sep 2020 01:55:25
	System	07 Sep 2020 01:55:25

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-06T21:55:12', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '9c467764-8e9d-4f19-a3f3-49aa0e8040d8' User entered 'None (0)'	System	07 Sep 2020 01:55:25
	System	07 Sep 2020 01:55:25

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-06T21:55:14', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '9c467764-8e9d-4f19-a3f3-49aa0e8040d8' User entered 'None (0)'	System	07 Sep 2020 01:55:25
	System	07 Sep 2020 01:55:25

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-06T21:55:16', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '9c467764-8e9d-4f19-a3f3-49aa0e8040d8' User entered 'None (0)'	System	07 Sep 2020 01:55:25
	System	07 Sep 2020 01:55:25

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-06T21:55:20', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '9c467764-8e9d-4f19-a3f3-49aa0e8040d8' User entered 'No (N)'	System	07 Sep 2020 01:55:25
	System	07 Sep 2020 01:55:25

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-06T21:55:24', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '9c467764-8e9d-4f19-a3f3-49aa0e8040d8' User entered '06 Sep 2020 21:55'	System	07 Sep 2020 01:55:25
	System	07 Sep 2020 01:55:25

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 19:39:06

US3542108

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 19:39:06

US3542108

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 04:56:42
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	10 Sep 2020 15:54:28

US3542108

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 04:56:42
User entered '9 Sep 2020'	(b) (4) Taylor Ladson (b) (4)	10 Sep 2020 15:54:28

US3542108

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4) (b) (4)	14 Sep 2020 04:56:42
User entered 'Contact Made (CONTACT MADE)'	Taylor Ladson (b) (4) (b) (4)	10 Sep 2020 15:54:28

US3542108

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4) (b) (4)	14 Sep 2020 04:56:42
User entered empty.	Taylor Ladson (b) (4) (b) (4)	10 Sep 2020 15:54:28

US3542108

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 04:56:42
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	10 Sep 2020 15:54:32

US3542108

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered 'l'	System	10 Sep 2020 15:54:32

US3542108

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:17:32
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	17 Sep 2020 17:02:50

US3542108

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:17:32
User entered '16 Sep 2020'	Madhu Balachandran (b) (4)	17 Sep 2020 17:02:50

US3542108

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:17:32
User entered 'Contact Made (CONTACT MADE)'	Madhu Balachandran (b) (4)	17 Sep 2020 17:02:50

US3542108

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4) (b) (4)	24 Sep 2020 03:17:32
User entered empty.	Madhu Balachandran (b) (4)	17 Sep 2020 17:02:50

US3542108

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:23:31
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	24 Sep 2020 17:26:25

US3542108

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered 'l'	System	24 Sep 2020 17:26:25

US3542108

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:23:31
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	24 Sep 2020 17:26:34

US3542108

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:23:31
User entered '23 Sep 2020'	(b) (4) Taylor Ladson (b) (4)	24 Sep 2020 17:26:34

US3542108

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:23:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Taylor Ladson (b) (4)	24 Sep 2020 17:26:34

US3542108

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4)	29 Sep 2020 04:23:31
User entered empty.	(b) (4)	
	Taylor Ladson (b) (4)	24 Sep 2020 17:26:34
	(b) (4)	

US3542108

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:23:31
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	24 Sep 2020 17:26:39

US3542108

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered 'l'	System	24 Sep 2020 17:26:39

US3542108

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:42:54
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:57:27

US3542108

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:32

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:42:54
User entered '29 Sep 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:57:27

US3542108

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:32

[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 07:09:50
User signature succeeded.	David Diemert (u) (4)	30 Sep 2020 22:42:54
User entered 'Clinic (Clinic)'	(b) (4) Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:57:27

US3542108

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered 'VISIT2'	System	30 Sep 2020 16:57:27

US3542108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User accepted default value 'Pre-Dose (PREDOSE)'	Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:59:22

US3542108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:42:54
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:59:22

US3542108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:42:54
User entered '29 Sep 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:59:22

US3542108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:42:54
User entered '10:00'	(b) (4) Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:59:22

US3542108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered '29 Sep 2020 10:00'	System	30 Sep 2020 16:59:22

US3542108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4)	30 Sep 2020 22:42:54
User entered '98.2' F	(b) (4) Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:59:22

US3542108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:42:54
User entered 'Oral (Oral)'	(b) (4) Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:59:22

US3542108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:42:54
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:59:22

US3542108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:42:54
User entered '68'	(b) (4) Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:59:22

US3542108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered 'bpm'	System	30 Sep 2020 16:59:22

US3542108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4)	30 Sep 2020 22:42:54
User entered '14'	(b) (4) Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:59:22

US3542108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered 'breaths/min'	System	30 Sep 2020 16:59:22

US3542108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4)	30 Sep 2020 22:42:54
User entered '123'	(b) (4) Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:59:22

US3542108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered 'mmHg'	System	30 Sep 2020 16:59:22

US3542108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4)	30 Sep 2020 22:42:54
User entered '72'	(b) (4) Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:59:22

US3542108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered 'mmHg'	System	30 Sep 2020 16:59:22

US3542108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User accepted default value 'Post-Dose (POSTDOSE)'	Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:59:22

US3542108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4)	30 Sep 2020 22:42:54
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:59:22

US3542108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:42:54
User entered '29 Sep 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:59:22

US3542108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:42:54
User entered '11:30'	(b) (4) Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:59:22

US3542108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered '29 Sep 2020 11:30'	System	30 Sep 2020 16:59:22

US3542108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4)	30 Sep 2020 22:42:54
User entered '98.4' F	(b) (4) Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:59:22

US3542108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:42:54
User entered 'Oral (Oral)'	(b) (4) Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:59:22

US3542108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:42:54
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:59:22

US3542108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4)	30 Sep 2020 22:42:54
User entered '64'	(b) (4) Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:59:22

US3542108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered 'bpm'	System	30 Sep 2020 16:59:22

US3542108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4)	30 Sep 2020 22:42:54
User entered '16'	(b) (4) Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:59:22

US3542108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered 'breaths/min'	System	30 Sep 2020 16:59:22

US3542108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4)	30 Sep 2020 22:42:54
User entered '124'	(b) (4) Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:59:22

US3542108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered 'mmHg'	System	30 Sep 2020 16:59:22

US3542108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4)	30 Sep 2020 22:42:54
User entered '79'	(b) (4) Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:59:22

US3542108

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered 'mmHg'	System	30 Sep 2020 16:59:22

US3542108

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:06:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:42:54
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:57:39

US3542108

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:06:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:42:54
User entered '29 Sep 2020'	Erika Faust (b) (4)	30 Sep 2020 16:57:39

US3542108

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:42:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 15:05:35

US3542108

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:32

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:42:54
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 15:05:35

US3542108

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:32

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 07:09:50
User signature succeeded.	David Diemert (u) (4)	30 Sep 2020 22:42:54
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 15:05:35

US3542108

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:32

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered 'MRNA-1273 OR PLACEBO'	System	29 Sep 2020 15:05:35

US3542108

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:42:54
User entered '29 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 15:31:53
User entered '09 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 15:05:35

US3542108

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:42:54
User entered '10:57'	(b) (4), (b) (6)	29 Sep 2020 15:05:35

US3542108

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered '29 Sep 2020 10:57'	System	29 Sep 2020 15:31:53
User entered '09 Sep 2020 10:57'	System	29 Sep 2020 15:05:35

US3542108

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:42:54
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	29 Sep 2020 15:05:35

US3542108

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:32

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered 'ONCE'	System	29 Sep 2020 15:05:35

US3542108

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:32

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered 'INTRAMUSCULAR'	System	29 Sep 2020 15:05:35

US3542108

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:42:54
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:57:59

US3542108

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:42:54
User entered '29 Sep 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:57:59

US3542108

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:42:54
User entered '10:15'	(b) (4) Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:57:59

US3542108

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered '29 Sep 2020 10:15'	System	30 Sep 2020 16:57:59

US3542108

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:06:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:42:54
User entered '29 Sep 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:58:11

US3542108

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:06:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:58:11

US3542108

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:06:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:42:54
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:58:11

US3542108

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:06:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:42:54
User entered '10:20'	(b) (4) Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:58:11

US3542108

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered '29 Sep 2020 10:20'	System	30 Sep 2020 16:58:11

US3542108

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:06:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:58:11

US3542108

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:06:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:42:54
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:58:11

US3542108

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:06:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:42:54
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:58:11

US3542108

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered empty.	System	30 Sep 2020 16:58:11

US3542108

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:42:54
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	30 Sep 2020 16:58:15

US3542108

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered 'I'	System	30 Sep 2020 16:58:15

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	29 Sep 2020 15:05:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-29T11:32:52', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '536779c3-247b-452e-99b4-1f6bf24f98bf' User entered 'Yes (Y)'	System	29 Sep 2020 15:33:10
	System	29 Sep 2020 15:33:10

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-29T11:32:57', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '536779c3-247b-452e-99b4-1f6bf24f98bf' User entered '98.4'	System	29 Sep 2020 15:33:10
	System	29 Sep 2020 15:33:10

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-29T11:33:03', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '536779c3-247b-452e-99b4-1f6bf24f98bf' User entered 'No (N)'	System	29 Sep 2020 15:33:10
	System	29 Sep 2020 15:33:10

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-29T11:33:06', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '536779c3-247b-452e-99b4-1f6bf24f98bf' User entered '29 Sep 2020 11:33'	System	29 Sep 2020 15:33:10
	System	29 Sep 2020 15:33:10

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '29 Sep 2020 11:17'	System	29 Sep 2020 15:31:53
User entered '09 Sep 2020 11:17'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '29 Sep 2020 13:47'	System	29 Sep 2020 15:31:53
User entered '09 Sep 2020 13:47'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	29 Sep 2020 15:05:35
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-29T21:02:08', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'd562c14f-2b58-4fa1-9d62-003b4d33dba4' User entered 'Yes (Y)'	System	30 Sep 2020 01:02:24
	System	30 Sep 2020 01:02:24

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-29T21:02:14', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'd562c14f-2b58-4fa1-9d62-003b4d33dba4' User entered '98.2'	System	30 Sep 2020 01:02:24
	System	30 Sep 2020 01:02:24

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-29T21:02:16', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'd562c14f-2b58-4fa1-9d62-003b4d33dba4' User entered 'No (N)'	System	30 Sep 2020 01:02:24
	System	30 Sep 2020 01:02:24

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-29T21:02:22', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'd562c14f-2b58-4fa1-9d62-003b4d33dba4' User entered '29 Sep 2020 21:02'	System	30 Sep 2020 01:02:24
	System	30 Sep 2020 01:02:24

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '29 Sep 2020 14:42'	System	29 Sep 2020 15:31:53
User entered '09 Sep 2020 14:42'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 15:31:53
User entered '10 Sep 2020 11:59'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	29 Sep 2020 15:05:35
User entered 'Day 2'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:06:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-30T16:03:54', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '6e8303ea-7807-42a3-b271-b578e2a3c4a1' User entered 'Yes (Y)'	System	30 Sep 2020 20:04:19
	System	30 Sep 2020 20:04:19

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:06:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-30T16:03:59', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '6e8303ea-7807-42a3-b271-b578e2a3c4a1' User entered '97.7'	System	30 Sep 2020 20:04:19
	System	30 Sep 2020 20:04:19

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-30T16:04:02', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '6e8303ea-7807-42a3-b271-b578e2a3c4a1' User entered 'Yes (Y)'	System	30 Sep 2020 20:04:19
	System	30 Sep 2020 20:04:19

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Participant was contacted, medication recorded' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 09:49:08
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-30T16:04:08', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '6e8303ea-7807-42a3-b271-b578e2a3c4a1' User entered '1'	Hannah Yellin (b) (4) (b) (4)	07 Oct 2020 17:40:46
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	30 Sep 2020 20:04:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-30T16:04:08', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '6e8303ea-7807-42a3-b271-b578e2a3c4a1' User entered '1'	System	30 Sep 2020 20:04:19
User entered '1'	System	30 Sep 2020 20:04:19

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:06:32

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-30T16:04:08', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '6e8303ea-7807-42a3-b271-b578e2a3c4a1' User entered '0'	System	30 Sep 2020 20:04:19
	System	30 Sep 2020 20:04:19

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:06:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-30T16:04:16', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '6e8303ea-7807-42a3-b271-b578e2a3c4a1' User entered '30 Sep 2020 16:04'	System	30 Sep 2020 20:04:19
	System	30 Sep 2020 20:04:19

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 15:31:53
User entered '10 Sep 2020 12:00'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 15:31:53
User entered '11 Sep 2020 11:59'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	29 Sep 2020 15:05:35
User entered 'Day 3'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:06:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-01T19:00:36', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '53e1bbd1-06f5-40cb-b80c-18fbf633ca76'	System	01 Oct 2020 23:00:54
User entered 'Yes (Y)'	System	01 Oct 2020 23:00:54

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:06:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-01T19:00:41', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '53e1bbd1-06f5-40cb-b80c-18fbf633ca76' User entered '97.7'	System	01 Oct 2020 23:00:54
	System	01 Oct 2020 23:00:54

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-01T19:00:44', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '53e1bbd1-06f5-40cb-b80c-18fbf633ca76'	System	01 Oct 2020 23:00:54
User entered 'Yes (Y)'	System	01 Oct 2020 23:00:54

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Participant was contacted, medication recorded' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 09:49:24
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-01T19:00:49', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '53e1bbd1-06f5-40cb-b80c-18fbf633ca76' User entered '1'	Hannah Yellin (b) (4) (b) (4)	07 Oct 2020 17:41:11
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	01 Oct 2020 23:00:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-01T19:00:49', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '53e1bbd1-06f5-40cb-b80c-18fbf633ca76' User entered '1'	System	01 Oct 2020 23:00:54
User entered '1'	System	01 Oct 2020 23:00:54

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:06:32

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-01T19:00:49', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '53e1bbd1-06f5-40cb-b80c-18fbf633ca76' User entered '0'	System	01 Oct 2020 23:00:54
	System	01 Oct 2020 23:00:54

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:06:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-01T19:00:51', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '53e1bbd1-06f5-40cb-b80c-18fbf633ca76' User entered '01 Oct 2020 19:00'	System	01 Oct 2020 23:00:54
	System	01 Oct 2020 23:00:54

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 15:31:53
User entered '11 Sep 2020 12:00'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 15:31:53
User entered '12 Sep 2020 11:59'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	29 Sep 2020 15:05:35
User entered 'Day 4'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:06:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-03T00:19:43', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'b77f87eb-defa-4a1f-ba4d-ab482208929a' User entered 'Yes (Y)'	System	03 Oct 2020 04:20:06
	System	03 Oct 2020 04:20:06

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:06:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-03T00:19:47', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'b77f87eb-defa-4a1f-ba4d-ab482208929a' User entered '97.1'	System	03 Oct 2020 04:20:06
	System	03 Oct 2020 04:20:06

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-03T00:19:53', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'b77f87eb-defa-4a1f-ba4d-ab482208929a'	System	03 Oct 2020 04:20:06
User entered 'Yes (Y)'	System	03 Oct 2020 04:20:06

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-03T00:20:01', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'b77f87eb-defa-4a1f-ba4d-ab482208929a' User entered '0'	System	03 Oct 2020 04:20:06
	System	03 Oct 2020 04:20:06

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:06:32

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Participant was contacted, medication recorded' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 09:48:51
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Hannah Yellin (b) (4)	07 Oct 2020 17:41:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-03T00:20:01', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'b77f87eb-defa-4a1f-ba4d-ab482208929a'	(b) (4)	
User entered '1'	System	03 Oct 2020 04:20:06
	System	03 Oct 2020 04:20:06
	System	03 Oct 2020 04:20:06

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:06:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-03T00:20:04', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'b77f87eb-defa-4a1f-ba4d-ab482208929a' User entered '03 Oct 2020 00:20'	System	03 Oct 2020 04:20:06
	System	03 Oct 2020 04:20:06

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 15:31:53
User entered '12 Sep 2020 12:00'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 15:31:53
User entered '13 Sep 2020 11:59'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	29 Sep 2020 15:05:35
User entered 'Day 5'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:06:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T05:46:43', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '47da6ab1-2b10-436a-9bf6-b6d0cd46921a' User entered 'Yes (Y)'	System	04 Oct 2020 09:47:07
	System	04 Oct 2020 09:47:07

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:06:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T05:46:47', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '47da6ab1-2b10-436a-9bf6-b6d0cd46921a' User entered '97.3'	System	04 Oct 2020 09:47:07
	System	04 Oct 2020 09:47:07

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T05:46:51', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '47da6ab1-2b10-436a-9bf6-b6d0cd46921a' User entered 'Yes (Y)'	System	04 Oct 2020 09:47:07
	System	04 Oct 2020 09:47:07

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T05:47:01', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '47da6ab1-2b10-436a-9bf6-b6d0cd46921a' User entered '0'	System	04 Oct 2020 09:47:07
	System	04 Oct 2020 09:47:07

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:06:32

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Participant was contacted and medication was added to the concomitant medication page' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 13:49:24
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Erika Faust (b) (4)	13 Nov 2020 14:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T05:47:01', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '47da6ab1-2b10-436a-9bf6-b6d0cd46921a' User entered '1'	(b) (4)	
	System	04 Oct 2020 09:47:07
	System	04 Oct 2020 09:47:07
	System	04 Oct 2020 09:47:07

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:06:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T05:47:04', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '47da6ab1-2b10-436a-9bf6-b6d0cd46921a' User entered '04 Oct 2020 05:47'	System	04 Oct 2020 09:47:07
	System	04 Oct 2020 09:47:07

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 15:31:53
User entered '13 Sep 2020 12:00'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 15:31:53
User entered '14 Sep 2020 11:59'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	29 Sep 2020 15:05:35
User entered 'Day 6'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:06:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T22:10:29', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '632bd3ed-72a8-4bb8-88ef-58befa22b616' User entered 'Yes (Y)'	System	05 Oct 2020 02:11:04
	System	05 Oct 2020 02:11:04

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:06:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T22:10:48', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '632bd3ed-72a8-4bb8-88ef-58befa22b616' User entered '97.5'	System	05 Oct 2020 02:11:04
	System	05 Oct 2020 02:11:04

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T22:10:57', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '632bd3ed-72a8-4bb8-88ef-58befa22b616'	System	05 Oct 2020 02:11:04
User entered 'No (N)'	System	05 Oct 2020 02:11:04

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:06:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T22:10:59', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '632bd3ed-72a8-4bb8-88ef-58befa22b616' User entered '04 Oct 2020 22:10'	System	05 Oct 2020 02:11:04
	System	05 Oct 2020 02:11:04

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 15:31:53
User entered '14 Sep 2020 12:00'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 15:31:53
User entered '15 Sep 2020 11:59'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	29 Sep 2020 15:05:35
User entered 'Day 7'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:06:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-05T21:37:04', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '5b078e8e-a860-4928-bfd6-ec9247a2862a' User entered 'Yes (Y)'	System	06 Oct 2020 01:37:27
	System	06 Oct 2020 01:37:27

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:06:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-05T21:37:08', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '5b078e8e-a860-4928-bfd6-ec9247a2862a' User entered '98.2'	System	06 Oct 2020 01:37:27
	System	06 Oct 2020 01:37:27

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-05T21:37:20', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '5b078e8e-a860-4928-bfd6-ec9247a2862a' User entered 'No (N)'	System	06 Oct 2020 01:37:27
	System	06 Oct 2020 01:37:27

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:06:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-05T21:37:25', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '5b078e8e-a860-4928-bfd6-ec9247a2862a' User entered '05 Oct 2020 21:37'	System	06 Oct 2020 01:37:27
	System	06 Oct 2020 01:37:27

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 15:31:53
User entered '15 Sep 2020 12:00'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 15:31:53
User entered '16 Sep 2020 11:59'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	29 Sep 2020 15:05:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-29T11:33:14', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'd7474b8e-ae4c-4bb5-9c30-bcd4dbde1023' User entered 'None (1)'	System	29 Sep 2020 15:33:31
	System	29 Sep 2020 15:33:31

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-29T11:33:17', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'd7474b8e-ae4c-4bb5-9c30-bcd4dbde1023' User entered 'No (N)'	System	29 Sep 2020 15:33:31
	System	29 Sep 2020 15:33:31

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-29T11:33:22', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'd7474b8e-ae4c-4bb5-9c30-bcd4dbde1023' User entered 'No (N)'	System	29 Sep 2020 15:33:31
	System	29 Sep 2020 15:33:31

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-29T11:33:26', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'd7474b8e-ae4c-4bb5-9c30-bcd4dbde1023' User entered 'None (1)'	System	29 Sep 2020 15:33:31
	System	29 Sep 2020 15:33:31

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-29T11:33:29', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'd7474b8e-ae4c-4bb5-9c30-bcd4dbde1023' User entered '29 Sep 2020 11:33'	System	29 Sep 2020 15:33:31
	System	29 Sep 2020 15:33:31

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '29 Sep 2020 11:17'	System	29 Sep 2020 15:31:53
User entered '09 Sep 2020 11:17'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '29 Sep 2020 13:47'	System	29 Sep 2020 15:31:53
User entered '09 Sep 2020 13:47'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	29 Sep 2020 15:05:35
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-29T21:02:37', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'c909ddd1-a8b9-4220-9610-32b457c1b765'	System	30 Sep 2020 01:03:37
User entered 'Does not interfere with activity (2)'	System	30 Sep 2020 01:03:37

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-29T21:02:44', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'c909ddd1-a8b9-4220-9610-32b457c1b765' User entered 'No (N)'	System	30 Sep 2020 01:03:37
	System	30 Sep 2020 01:03:37

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-29T21:02:53', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'c909ddd1-a8b9-4220-9610-32b457c1b765'	System	30 Sep 2020 01:03:37
User entered 'No (N)'	System	30 Sep 2020 01:03:37

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-29T21:03:06', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'c909ddd1-a8b9-4220-9610-32b457c1b765'	System	30 Sep 2020 01:03:37
User entered 'None (1)'	System	30 Sep 2020 01:03:37

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-29T21:03:09', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'c909ddd1-a8b9-4220-9610-32b457c1b765' User entered '29 Sep 2020 21:03'	System	30 Sep 2020 01:03:37
	System	30 Sep 2020 01:03:37

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '29 Sep 2020 14:42'	System	29 Sep 2020 15:31:53
User entered '09 Sep 2020 14:42'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 15:31:53
User entered '10 Sep 2020 11:59'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	29 Sep 2020 15:05:35
User entered 'Day 2'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-30T16:04:54', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '5b7ca9c0-fb69-4c06-9743-1f79cbeadfea' User entered 'Does not interfere with activity (2)'	System	30 Sep 2020 20:05:16
	System	30 Sep 2020 20:05:16

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-30T16:04:56', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '5b7ca9c0-fb69-4c06-9743-1f79cbeadfea' User entered 'No (N)'	System	30 Sep 2020 20:05:16
	System	30 Sep 2020 20:05:16

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-30T16:05:05', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '5b7ca9c0-fb69-4c06-9743-1f79cbeadfea' User entered 'No (N)'	System	30 Sep 2020 20:05:16
	System	30 Sep 2020 20:05:16

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-30T16:05:10', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '5b7ca9c0-fb69-4c06-9743-1f79cbeadfea' User entered 'None (1)'	System	30 Sep 2020 20:05:16
	System	30 Sep 2020 20:05:16

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-30T16:05:13', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '5b7ca9c0-fb69-4c06-9743-1f79cbeadfea' User entered '30 Sep 2020 16:05'	System	30 Sep 2020 20:05:16
	System	30 Sep 2020 20:05:16

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 15:31:53
User entered '10 Sep 2020 12:00'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 15:31:53
User entered '11 Sep 2020 11:59'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	29 Sep 2020 15:05:35
User entered 'Day 3'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-01T19:01:03', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '2702dfd0-65d5-4031-93a6-60717779219c'	System	01 Oct 2020 23:01:22
User entered 'Does not interfere with activity (2)'	System	01 Oct 2020 23:01:22

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-01T19:01:05', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '2702dfd0-65d5-4031-93a6-60717779219c' User entered 'No (N)'	System	01 Oct 2020 23:01:22
	System	01 Oct 2020 23:01:22

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-01T19:01:10', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '2702dfd0-65d5-4031-93a6-60717779219c' User entered 'No (N)'	System	01 Oct 2020 23:01:22
	System	01 Oct 2020 23:01:22

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-01T19:01:15', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '2702dfd0-65d5-4031-93a6-60717779219c' User entered 'None (1)'	System	01 Oct 2020 23:01:22
	System	01 Oct 2020 23:01:22

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-01T19:01:17', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '2702dfd0-65d5-4031-93a6-60717779219c' User entered '01 Oct 2020 19:01'	System	01 Oct 2020 23:01:22
	System	01 Oct 2020 23:01:22

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 15:31:53
User entered '11 Sep 2020 12:00'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 15:31:53
User entered '12 Sep 2020 11:59'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	29 Sep 2020 15:05:35
User entered 'Day 4'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-03T00:20:09', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'f19c21e2-a147-420d-a47a-bdf88b2a9c13'	System	03 Oct 2020 04:20:22
User entered 'None (1)'	System	03 Oct 2020 04:20:22

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-03T00:20:12', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'f19c21e2-a147-420d-a47a-bdf88b2a9c13' User entered 'No (N)'	System	03 Oct 2020 04:20:22
	System	03 Oct 2020 04:20:22

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-03T00:20:14', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'f19c21e2-a147-420d-a47a-bdf88b2a9c13' User entered 'No (N)'	System	03 Oct 2020 04:20:22
	System	03 Oct 2020 04:20:22

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-03T00:20:18', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'f19c21e2-a147-420d-a47a-bdf88b2a9c13'	System	03 Oct 2020 04:20:22
User entered 'None (1)'	System	03 Oct 2020 04:20:22

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-03T00:20:20', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'f19c21e2-a147-420d-a47a-bdf88b2a9c13' User entered '03 Oct 2020 00:20'	System	03 Oct 2020 04:20:22
	System	03 Oct 2020 04:20:22

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 15:31:53
User entered '12 Sep 2020 12:00'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 15:31:53
User entered '13 Sep 2020 11:59'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	29 Sep 2020 15:05:35
User entered 'Day 5'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T05:47:09', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '3d08579f-9b2c-446a-b647-c97c185375f0' User entered 'None (1)'	System	04 Oct 2020 09:47:20
	System	04 Oct 2020 09:47:20

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T05:47:11', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '3d08579f-9b2c-446a-b647-c97c185375f0' User entered 'No (N)'	System	04 Oct 2020 09:47:20
	System	04 Oct 2020 09:47:20

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T05:47:13', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '3d08579f-9b2c-446a-b647-c97c185375f0' User entered 'No (N)'	System	04 Oct 2020 09:47:20
	System	04 Oct 2020 09:47:20

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T05:47:17', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '3d08579f-9b2c-446a-b647-c97c185375f0' User entered 'None (1)'	System	04 Oct 2020 09:47:20
	System	04 Oct 2020 09:47:20

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T05:47:19', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '3d08579f-9b2c-446a-b647-c97c185375f0' User entered '04 Oct 2020 05:47'	System	04 Oct 2020 09:47:20
	System	04 Oct 2020 09:47:20

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 15:31:53
User entered '13 Sep 2020 12:00'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 15:31:53
User entered '14 Sep 2020 11:59'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	29 Sep 2020 15:05:35
User entered 'Day 6'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T22:11:05', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'd4c457a2-baf2-4817-aa1f-c817ad24c8d4'	System	05 Oct 2020 02:11:16
User entered 'None (1)'	System	05 Oct 2020 02:11:16

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T22:11:07', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'd4c457a2-baf2-4817-aa1f-c817ad24c8d4'	System	05 Oct 2020 02:11:16
User entered 'No (N)'	System	05 Oct 2020 02:11:16

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T22:11:09', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'd4c457a2-baf2-4817-aa1f-c817ad24c8d4'	System	05 Oct 2020 02:11:16
User entered 'No (N)'	System	05 Oct 2020 02:11:16

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T22:11:13', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'd4c457a2-baf2-4817-aa1f-c817ad24c8d4'	System	05 Oct 2020 02:11:16
User entered 'None (1)'	System	05 Oct 2020 02:11:16

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T22:11:15', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'd4c457a2-baf2-4817-aa1f-c817ad24c8d4' User entered '04 Oct 2020 22:11'	System	05 Oct 2020 02:11:16
	System	05 Oct 2020 02:11:16

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 15:31:53
User entered '14 Sep 2020 12:00'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 15:31:53
User entered '15 Sep 2020 11:59'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	29 Sep 2020 15:05:35
User entered 'Day 7'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-05T21:37:40', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'ccfaa07e-31c1-4c8f-ad13-c1467eb99338' User entered 'None (1)'	System	06 Oct 2020 01:37:57
	System	06 Oct 2020 01:37:57

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-05T21:37:42', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'ccfaa07e-31c1-4c8f-ad13-c1467eb99338' User entered 'No (N)'	System	06 Oct 2020 01:37:57
	System	06 Oct 2020 01:37:57

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-05T21:37:44', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'ccfaa07e-31c1-4c8f-ad13-c1467eb99338' User entered 'No (N)'	System	06 Oct 2020 01:37:57
	System	06 Oct 2020 01:37:57

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-05T21:37:50', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'ccfaa07e-31c1-4c8f-ad13-c1467eb99338' User entered 'None (1)'	System	06 Oct 2020 01:37:57
	System	06 Oct 2020 01:37:57

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-05T21:37:52', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'ccfaa07e-31c1-4c8f-ad13-c1467eb99338' User entered '05 Oct 2020 21:37'	System	06 Oct 2020 01:37:57
	System	06 Oct 2020 01:37:57

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 15:31:53
User entered '15 Sep 2020 12:00'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 15:31:53
User entered '16 Sep 2020 11:59'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	29 Sep 2020 15:05:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-29T11:33:33', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '2ce81551-a7db-44a2-b867-9c47fcda64c7' User entered 'None (0)'	System	29 Sep 2020 15:33:50
	System	29 Sep 2020 15:33:50

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-29T11:33:35', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '2ce81551-a7db-44a2-b867-9c47fcda64c7' User entered 'None (0)'	System	29 Sep 2020 15:33:50
	System	29 Sep 2020 15:33:50

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-29T11:33:36', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '2ce81551-a7db-44a2-b867-9c47fcda64c7' User entered 'None (0)'	System	29 Sep 2020 15:33:50
	System	29 Sep 2020 15:33:50

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-29T11:33:39', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '2ce81551-a7db-44a2-b867-9c47fcda64c7' User entered 'None (0)'	System	29 Sep 2020 15:33:50
	System	29 Sep 2020 15:33:50

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-29T11:33:41', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '2ce81551-a7db-44a2-b867-9c47fcda64c7' User entered 'None (0)'	System	29 Sep 2020 15:33:50
	System	29 Sep 2020 15:33:50

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-29T11:33:42', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '2ce81551-a7db-44a2-b867-9c47fcda64c7' User entered 'None (0)'	System	29 Sep 2020 15:33:50
	System	29 Sep 2020 15:33:50

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-29T11:33:45', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '2ce81551-a7db-44a2-b867-9c47fcda64c7' User entered 'No (N)'	System	29 Sep 2020 15:33:50
	System	29 Sep 2020 15:33:50

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-29T11:33:48', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '2ce81551-a7db-44a2-b867-9c47fcda64c7' User entered '29 Sep 2020 11:33'	System	29 Sep 2020 15:33:50
	System	29 Sep 2020 15:33:50

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '29 Sep 2020 11:17'	System	29 Sep 2020 15:31:53
User entered '09 Sep 2020 11:17'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '29 Sep 2020 13:47'	System	29 Sep 2020 15:31:53
User entered '09 Sep 2020 13:47'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	29 Sep 2020 15:05:35
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-29T21:03:12', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '0a191cc6-c917-47ae-a395-30c00c699b43' User entered 'None (0)'	System	30 Sep 2020 01:03:53
	System	30 Sep 2020 01:03:53

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-29T21:03:22', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '0a191cc6-c917-47ae-a395-30c00c699b43' User entered 'None (0)'	System	30 Sep 2020 01:03:53
	System	30 Sep 2020 01:03:53

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-29T21:03:24', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '0a191cc6-c917-47ae-a395-30c00c699b43' User entered 'None (0)'	System	30 Sep 2020 01:03:53
	System	30 Sep 2020 01:03:53

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-29T21:03:29', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '0a191cc6-c917-47ae-a395-30c00c699b43' User entered 'None (0)'	System	30 Sep 2020 01:03:53
	System	30 Sep 2020 01:03:53

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-29T21:03:31', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '0a191cc6-c917-47ae-a395-30c00c699b43' User entered 'None (0)'	System	30 Sep 2020 01:03:53
	System	30 Sep 2020 01:03:53

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-29T21:03:33', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '0a191cc6-c917-47ae-a395-30c00c699b43' User entered 'None (0)'	System	30 Sep 2020 01:03:53
	System	30 Sep 2020 01:03:53

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-29T21:03:37', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '0a191cc6-c917-47ae-a395-30c00c699b43' User entered 'No (N)'	System	30 Sep 2020 01:03:53
	System	30 Sep 2020 01:03:53

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-29T21:03:39', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '0a191cc6-c917-47ae-a395-30c00c699b43' User entered '29 Sep 2020 21:03'	System	30 Sep 2020 01:03:53
	System	30 Sep 2020 01:03:53

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '29 Sep 2020 14:42'	System	29 Sep 2020 15:31:53
User entered '09 Sep 2020 14:42'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 15:31:53
User entered '10 Sep 2020 11:59'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	29 Sep 2020 15:05:35
User entered 'Day 2'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-30T16:05:29', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '11b5f8e8-654c-4e8e-965d-03c46e86fd79'	System	30 Sep 2020 20:06:12
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		30 Sep 2020 20:06:12

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-30T16:05:38', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '11b5f8e8-654c-4e8e-965d-03c46e86fd79'	System	30 Sep 2020 20:06:12
User entered 'Significant; prevents daily activity (3)'	System	30 Sep 2020 20:06:12

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-30T16:05:41', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '11b5f8e8-654c-4e8e-965d-03c46e86fd79'	System	30 Sep 2020 20:06:12
User entered 'Significant; prevents daily activity (3)'	System	30 Sep 2020 20:06:12

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-30T16:05:55', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '11b5f8e8-654c-4e8e-965d-03c46e86fd79'	System	30 Sep 2020 20:06:12
User entered 'Significant; prevents daily activity (3)'	System	30 Sep 2020 20:06:12

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-30T16:05:58', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '11b5f8e8-654c-4e8e-965d-03c46e86fd79' User entered 'None (0)'	System	30 Sep 2020 20:06:12
	System	30 Sep 2020 20:06:12

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-30T16:06:02', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '11b5f8e8-654c-4e8e-965d-03c46e86fd79'	System	30 Sep 2020 20:06:12
User entered 'Some interference with activity not requiring medical attention (2)'	System	30 Sep 2020 20:06:12

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-30T16:06:07', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '11b5f8e8-654c-4e8e-965d-03c46e86fd79'	System	30 Sep 2020 20:06:12
User entered 'No (N)'	System	30 Sep 2020 20:06:12

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-09-30T16:06:09', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '11b5f8e8-654c-4e8e-965d-03c46e86fd79' User entered '30 Sep 2020 16:06'	System	30 Sep 2020 20:06:12
	System	30 Sep 2020 20:06:12

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 15:31:53
User entered '10 Sep 2020 12:00'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 15:31:53
User entered '11 Sep 2020 11:59'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	29 Sep 2020 15:05:35
User entered 'Day 3'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-01T18:59:32', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '2929deb8-bec0-452b-834e-5ef64c460c75'	System	01 Oct 2020 23:00:36
User entered 'No interference with activity (1)'	System	01 Oct 2020 23:00:36

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-01T18:59:48', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '2929deb8-bec0-452b-834e-5cf64c460c75' User entered 'Significant; prevents daily activity (3)'	System	01 Oct 2020 23:00:36
	System	01 Oct 2020 23:00:36

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-01T18:59:58', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '2929deb8-bec0-452b-834e-5ef64c460c75' User entered 'Some interference with activity (2)'	System	01 Oct 2020 23:00:36
	System	01 Oct 2020 23:00:36

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-01T19:00:08', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '2929deb8-bec0-452b-834e-5cf64c460c75' User entered 'None (0)'	System	01 Oct 2020 23:00:36
	System	01 Oct 2020 23:00:36

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-01T19:00:13', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '2929deb8-bec0-452b-834e-5cf64c460c75' User entered 'None (0)'	System	01 Oct 2020 23:00:36
	System	01 Oct 2020 23:00:36

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-01T19:00:19', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '2929deb8-bec0-452b-834e-5ef64c460c75'	System	01 Oct 2020 23:00:36
User entered 'Some interference with activity not requiring medical attention (2)'	System	01 Oct 2020 23:00:36

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-01T19:00:29', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '2929deb8-bec0-452b-834e-5cf64c460c75'	System	01 Oct 2020 23:00:36
User entered 'Yes (Y)'	System	01 Oct 2020 23:00:36

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-01T19:00:31', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '2929deb8-bec0-452b-834e-5cf64c460c75' User entered '01 Oct 2020 19:00'	System	01 Oct 2020 23:00:36
	System	01 Oct 2020 23:00:36

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 15:31:53
User entered '11 Sep 2020 12:00'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 15:31:53
User entered '12 Sep 2020 11:59'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	29 Sep 2020 15:05:35
User entered 'Day 4'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-03T00:21:25', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '6fea96c8-cd87-40f5-98ba-86fefef6eca1'	System	03 Oct 2020 04:21:30
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	03 Oct 2020 04:21:30

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-03T00:20:51', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '6fea96c8-cd87-40f5-98ba-86fefef6eca1' User entered 'None (0)'	System	03 Oct 2020 04:21:30
	System	03 Oct 2020 04:21:30

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-03T00:20:59', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '6fea96c8-cd87-40f5-98ba-86fefef6ecaf' User entered 'None (0)'	System	03 Oct 2020 04:21:30
	System	03 Oct 2020 04:21:30

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-03T00:21:02', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '6fea96c8-cd87-40f5-98ba-86fefef6ecaf' User entered 'None (0)'	System	03 Oct 2020 04:21:30
	System	03 Oct 2020 04:21:30

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-03T00:21:04', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '6fea96c8-cd87-40f5-98ba-86fefef6ecaf' User entered 'None (0)'	System	03 Oct 2020 04:21:30
	System	03 Oct 2020 04:21:30

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-03T00:21:14', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '6fea96c8-cd87-40f5-98ba-86fefef6ecaf' User entered 'None (0)'	System	03 Oct 2020 04:21:30
	System	03 Oct 2020 04:21:30

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-03T00:21:20', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '6fea96c8-cd87-40f5-98ba-86fefef6ecaf'	System	03 Oct 2020 04:21:30
User entered 'No (N)'	System	03 Oct 2020 04:21:30

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-03T00:21:29', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '6fea96c8-cd87-40f5-98ba-86fefef6ecaf' User entered '03 Oct 2020 00:21'	System	03 Oct 2020 04:21:30
	System	03 Oct 2020 04:21:30

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 15:31:53
User entered '12 Sep 2020 12:00'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 15:31:53
User entered '13 Sep 2020 11:59'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	29 Sep 2020 15:05:35
User entered 'Day 5'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T05:47:23', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'ae96310f-6bbc-4266-87ee-653a81ae617d' User entered 'None (0)'	System	04 Oct 2020 09:47:47
	System	04 Oct 2020 09:47:47

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T05:47:26', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'ae96310f-6bbc-4266-87ee-653a81ae617d' User entered 'None (0)'	System	04 Oct 2020 09:47:47
	System	04 Oct 2020 09:47:47

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T05:47:28', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'ae96310f-6bbc-4266-87ee-653a81ae617d' User entered 'None (0)'	System	04 Oct 2020 09:47:47
	System	04 Oct 2020 09:47:47

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T05:47:29', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'ae96310f-6bbc-4266-87ee-653a81ae617d' User entered 'None (0)'	System	04 Oct 2020 09:47:47
	System	04 Oct 2020 09:47:47

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T05:47:31', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'ae96310f-6bbc-4266-87ee-653a81ae617d' User entered 'None (0)'	System	04 Oct 2020 09:47:47
	System	04 Oct 2020 09:47:47

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T05:47:33', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'ae96310f-6bbc-4266-87ee-653a81ae617d' User entered 'None (0)'	System	04 Oct 2020 09:47:47
	System	04 Oct 2020 09:47:47

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T05:47:41', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'ae96310f-6bbc-4266-87ee-653a81ae617d' User entered 'Yes (Y)'	System	04 Oct 2020 09:47:47
	System	04 Oct 2020 09:47:47

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T05:47:44', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'ae96310f-6bbc-4266-87ee-653a81ae617d' User entered '04 Oct 2020 05:47'	System	04 Oct 2020 09:47:47
	System	04 Oct 2020 09:47:47

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 15:31:53
User entered '13 Sep 2020 12:00'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 15:31:53
User entered '14 Sep 2020 11:59'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	29 Sep 2020 15:05:35
User entered 'Day 6'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T22:11:19', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '97576189-b08e-4e44-b6e5-20cbf74775b6' User entered 'None (0)'	System	05 Oct 2020 02:11:43
	System	05 Oct 2020 02:11:43

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T22:11:22', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '97576189-b08e-4e44-b6e5-20cbf74775b6' User entered 'None (0)'	System	05 Oct 2020 02:11:43
	System	05 Oct 2020 02:11:43

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T22:11:24', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '97576189-b08e-4e44-b6e5-20cbf74775b6' User entered 'None (0)'	System	05 Oct 2020 02:11:43
	System	05 Oct 2020 02:11:43

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T22:11:26', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '97576189-b08e-4e44-b6e5-20cbf74775b6' User entered 'None (0)'	System	05 Oct 2020 02:11:43
	System	05 Oct 2020 02:11:43

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T22:11:28', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '97576189-b08e-4e44-b6e5-20cbf74775b6' User entered 'None (0)'	System	05 Oct 2020 02:11:43
	System	05 Oct 2020 02:11:43

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T22:11:31', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '97576189-b08e-4e44-b6e5-20cbf74775b6' User entered 'None (0)'	System	05 Oct 2020 02:11:43
	System	05 Oct 2020 02:11:43

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T22:11:37', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '97576189-b08e-4e44-b6e5-20cbf74775b6' User entered 'Yes (Y)'	System	05 Oct 2020 02:11:43
	System	05 Oct 2020 02:11:43

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-04T22:11:40', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '97576189-b08e-4e44-b6e5-20cbf74775b6' User entered '04 Oct 2020 22:11'	System	05 Oct 2020 02:11:43
	System	05 Oct 2020 02:11:43

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 15:31:53
User entered '14 Sep 2020 12:00'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 15:31:53
User entered '15 Sep 2020 11:59'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	29 Sep 2020 15:05:35
User entered 'Day 7'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-05T21:37:56', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '5e80c34a-7a38-4ab7-b074-4a2a1217ee58' User entered 'None (0)'	System	06 Oct 2020 01:38:52
	System	06 Oct 2020 01:38:52

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-05T21:38:15', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '5e80c34a-7a38-4ab7-b074-4a2a1217ee58'	System	06 Oct 2020 01:38:52
User entered 'No interference with activity (1)'	System	06 Oct 2020 01:38:52

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-05T21:38:19', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '5e80c34a-7a38-4ab7-b074-4a2a1217ee58' User entered 'None (0)'	System	06 Oct 2020 01:38:52
	System	06 Oct 2020 01:38:52

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-05T21:38:27', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '5e80c34a-7a38-4ab7-b074-4a2a1217ee58' User entered 'None (0)'	System	06 Oct 2020 01:38:52
	System	06 Oct 2020 01:38:52

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-05T21:38:34', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '5e80c34a-7a38-4ab7-b074-4a2a1217ee58'	System	06 Oct 2020 01:38:52
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	06 Oct 2020 01:38:52

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-05T21:38:37', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '5e80c34a-7a38-4ab7-b074-4a2a1217ee58' User entered 'None (0)'	System	06 Oct 2020 01:38:52
	System	06 Oct 2020 01:38:52

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-05T21:38:47', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '5e80c34a-7a38-4ab7-b074-4a2a1217ee58' User entered 'Yes (Y)'	System	06 Oct 2020 01:38:52
	System	06 Oct 2020 01:38:52

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-05T21:38:49', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '5e80c34a-7a38-4ab7-b074-4a2a1217ee58' User entered '05 Oct 2020 21:38'	System	06 Oct 2020 01:38:52
	System	06 Oct 2020 01:38:52

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 15:31:53
User entered '15 Sep 2020 12:00'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 15:31:53
User entered '16 Sep 2020 11:59'	System	29 Sep 2020 15:05:35

US3542108

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	06 Oct 2020 01:38:52
User entered 'Day 8'	System	06 Oct 2020 01:38:52

US3542108

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:06:32

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-07T00:03:13', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '1d59278b-423b-4a2e-8ca2-582233241b7a' User entered 'None (0)'	System	07 Oct 2020 04:03:21
	System	07 Oct 2020 04:03:21

US3542108

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:06:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-07T00:03:16', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '1d59278b-423b-4a2e-8ca2-582233241b7a' User entered '07 Oct 2020 00:03'	System	07 Oct 2020 04:03:21
	System	07 Oct 2020 04:03:21

US3542108

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '06 Oct 2020 12:00'	System	06 Oct 2020 01:38:52

US3542108

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 01:38:52

US3542108

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	06 Oct 2020 01:38:52
User entered 'Day 8'	System	06 Oct 2020 01:38:52

US3542108

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 08:06:32

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-07T00:03:20', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '7c3637e4-82cb-4fc3-b479-8c81d1d13bec' User entered 'None (0)'	System	07 Oct 2020 04:03:26
	System	07 Oct 2020 04:03:26

US3542108

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 08:06:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-07T00:03:23', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '7c3637e4-82cb-4fc3-b479-8c81d1d13bec' User entered '07 Oct 2020 00:03'	System	07 Oct 2020 04:03:26
	System	07 Oct 2020 04:03:26

US3542108

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '06 Oct 2020 12:00'	System	06 Oct 2020 01:38:52

US3542108

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 01:38:52

US3542108

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	06 Oct 2020 01:38:52
User entered 'Day 8'	System	06 Oct 2020 01:38:52

US3542108

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-07T00:03:27', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'ba4b13d9-4478-4531-96cf-e0fbdf24f519' User entered 'No (N)'	System	07 Oct 2020 04:03:33
	System	07 Oct 2020 04:03:33

US3542108

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:06:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-10-07T00:03:30', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'ba4b13d9-4478-4531-96cf-e0fbdf24f519' User entered '07 Oct 2020 00:03'	System	07 Oct 2020 04:03:33
	System	07 Oct 2020 04:03:33

US3542108

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:06:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '06 Oct 2020 12:00'	System	06 Oct 2020 01:38:52

US3542108

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:06:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 01:38:52

US3542108

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	07 Oct 2020 16:42:56

US3542108

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered '6 Oct 2020'	Madhu Balachandran (b) (4)	07 Oct 2020 16:42:56

US3542108

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4) (b) (4)	08 Oct 2020 03:01:20
User entered 'Contact Made (CONTACT MADE)'	Madhu Balachandran (b) (4)	07 Oct 2020 16:42:56

US3542108

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4) (b) (4)	08 Oct 2020 03:01:20
User entered empty.	Madhu Balachandran (b) (4)	07 Oct 2020 16:42:56

US3542108

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	07 Oct 2020 16:43:03

US3542108

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered 'l'	System	07 Oct 2020 16:43:03

US3542108

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 02:53:34
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	14 Oct 2020 17:47:18

US3542108

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 02:53:34
User entered '14 Oct 2020'	(b) (4) Taylor Ladson (b) (4)	14 Oct 2020 17:47:18

US3542108

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4) (b) (4)	16 Oct 2020 02:53:34
User entered 'Contact Made (CONTACT MADE)'	Taylor Ladson (b) (4) (b) (4)	14 Oct 2020 17:47:18

US3542108

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4) (b) (4)	16 Oct 2020 02:53:34
User entered empty.	Taylor Ladson (b) (4) (b) (4)	14 Oct 2020 17:47:18

US3542108

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 02:53:34
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	14 Oct 2020 17:47:23

US3542108

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered 'l'	System	14 Oct 2020 17:47:23

US3542108

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:50:13
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	21 Oct 2020 18:51:24

US3542108

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:50:13
User entered '20 Oct 2020'	Madhu Balachandran (b) (4)	21 Oct 2020 18:51:24

US3542108

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4) (b) (4)	23 Oct 2020 13:50:13
User entered 'Contact Made (CONTACT MADE)'	Madhu Balachandran (b) (4)	21 Oct 2020 18:51:24

US3542108

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4) (b) (4)	23 Oct 2020 13:50:13
User entered empty.	Madhu Balachandran (b) (4)	21 Oct 2020 18:51:24

US3542108

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:50:13
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	21 Oct 2020 18:51:28

US3542108

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered 'l'	System	21 Oct 2020 18:51:28

US3542108

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:59
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:23:06

US3542108

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:32

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:59
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered '27 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:23:06

US3542108

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:32

[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 07:09:59
User signature succeeded.	David Diemert (u) (4)	30 Oct 2020 01:19:07
User entered 'Clinic (Clinic)'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:23:06

US3542108

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:59
User entered 'VISIT3'	System	28 Oct 2020 15:23:06

US3542108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:59
User signature succeeded.	David Diemert (u) (4)	30 Oct 2020 01:19:07
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:24:05

US3542108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:59
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered '27 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:24:05

US3542108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:59
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered '11:16'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:24:05

US3542108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:59
User entered '27 Oct 2020 11:16'	System	28 Oct 2020 15:24:05

US3542108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:59
User signature succeeded.	David Diemert (u) (4)	30 Oct 2020 01:19:07
User entered '98.2' F	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:24:05

US3542108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:59
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered 'Oral (Oral)'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:24:05

US3542108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:59
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:24:05

US3542108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:59
User signature succeeded.	David Diemert (u) (4)	30 Oct 2020 01:19:07
User entered '86'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:24:05

US3542108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:59
User entered 'bpm'	System	28 Oct 2020 15:24:05

US3542108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:59
User signature succeeded.	David Diemert (u) (4)	30 Oct 2020 01:19:07
User entered '16'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:24:05

US3542108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:59
User entered 'breaths/min'	System	28 Oct 2020 15:24:05

US3542108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:59
User signature succeeded.	David Diemert (u) (4)	30 Oct 2020 01:19:07
User entered '115'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:24:05

US3542108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:59
User entered 'mmHg'	System	28 Oct 2020 15:24:05

US3542108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:59
User signature succeeded.	David Diemert (u) (4)	30 Oct 2020 01:19:07
User entered '72'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:24:05

US3542108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:59
User entered 'mmHg'	System	28 Oct 2020 15:24:05

US3542108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:59

US3542108

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:59

US3542108

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:06:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4)	30 Oct 2020 01:19:07
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:23:14

US3542108

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:06:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:23:14

US3542108

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:23:30

US3542108

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered '27 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:23:30

US3542108

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered '11:24'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:23:30

US3542108

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered '27 Oct 2020 11:24'	System	28 Oct 2020 15:23:30

US3542108

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:23:36

US3542108

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered 'I'	System	28 Oct 2020 15:23:36

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	31 Aug 2020 19:39:06
User entered 'Day 64'	System	31 Aug 2020 19:39:06

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-11-01T17:33:08', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '3b6748e7-1ec9-466e-b570-a68e46800098' User entered 'No (N)'	System	01 Nov 2020 22:33:20
	System	01 Nov 2020 22:33:20

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-11-01T17:33:13', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '3b6748e7-1ec9-466e-b570-a68e46800098'	System	01 Nov 2020 22:33:20
User entered 'No (N)'	System	01 Nov 2020 22:33:20

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F123446-68A9-404F-8B0F-EBAE55505700)', Time: '2020-11-01T17:33:16', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '3b6748e7-1ec9-466e-b570-a68e46800098' User entered '01 Nov 2020 17:33:16'	System	01 Nov 2020 22:33:20
	System	01 Nov 2020 22:33:20

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	31 Aug 2020 19:39:06
User entered '31 Oct 2020 00:01'	System	31 Aug 2020 19:39:06

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:49:04
Data entry locked.	System	31 Aug 2020 19:39:06
User entered '04 Nov 2020 23:59'	System	31 Aug 2020 19:39:06

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12
Data entry locked.	System	31 Aug 2020 19:39:06
User entered 'Day 71'	System	31 Aug 2020 19:39:06

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12
Data entry locked.	System	31 Aug 2020 19:39:06
User entered '07 Nov 2020 00:01'	System	31 Aug 2020 19:39:06

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12
Data entry locked.	System	31 Aug 2020 19:39:06
User entered '11 Nov 2020 23:59'	System	31 Aug 2020 19:39:06

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12
Data entry locked.	System	31 Aug 2020 19:39:06
User entered 'Day 78'	System	31 Aug 2020 19:39:06

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

US3542108

Folder: Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12

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Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12
Data entry locked.	System	31 Aug 2020 19:39:06
User entered '14 Nov 2020 00:01'	System	31 Aug 2020 19:39:06

US3542108

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:10:12
Data entry locked.	System	31 Aug 2020 19:39:06
User entered '18 Nov 2020 23:59'	System	31 Aug 2020 19:39:06

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 21:10:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-01-01T10:35:02', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '6a22b395-767a-4d06-aaf7-2a1daf1cbd21' User entered 'No (N)'	System	01 Jan 2021 15:35:16
	System	01 Jan 2021 15:35:16

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-01-01T10:35:10', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '6a22b395-767a-4d06-aaf7-2a1daf1cbd21' User entered 'No (N)'	System	01 Jan 2021 15:35:16

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-01-01T10:35:13', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '6a22b395-767a-4d06-aaf7-2a1daf1cbd21' User entered '01 Jan 2021 10:35:13'	System	01 Jan 2021 15:35:16
	System	01 Jan 2021 15:35:16

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-01-08T11:37:18', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'fd06b351-8d7c-41c4-9f80-e79f3a1f3aeb' User entered 'No (N)'	System	08 Jan 2021 16:37:31

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-01-08T11:37:24', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'fd06b351-8d7c-41c4-9f80-e79f3a1f3aeb'	System	08 Jan 2021 16:37:31
User entered 'No (N)'	System	08 Jan 2021 16:37:31

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-01-08T11:37:26', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'fd06b351-8d7c-41c4-9f80-e79f3a1f3aeb' User entered '08 Jan 2021 11:37:26'	System	08 Jan 2021 16:37:31

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-01-16T09:52:49', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'ddd64d0d-df03-4364-aa80-a6719788cf5f' User entered 'No (N)'	System	16 Jan 2021 14:52:59
	System	16 Jan 2021 14:52:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-01-16T09:52:54', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'ddd64d0d-df03-4364-aa80-a6719788cf5f'	System	16 Jan 2021 14:52:59
User entered 'No (N)'	System	16 Jan 2021 14:52:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-01-16T09:52:56', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'ddd64d0d-df03-4364-aa80-a6719788cf5f' User entered '16 Jan 2021 09:52:56'	System	16 Jan 2021 14:52:59
	System	16 Jan 2021 14:52:59

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-01-21T11:57:05', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '30223bd4-a0c5-41c9-bfe7-445f332c60d0' User entered 'No (N)'	System	21 Jan 2021 16:57:17

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-01-21T11:57:10', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '30223bd4-a0c5-41c9-bfe7-445f332c60d0' User entered 'No (N)'	System	21 Jan 2021 16:57:17

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-01-21T11:57:13', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '30223bd4-a0c5-41c9-bfe7-445f332c60d0' User entered '21 Jan 2021 11:57:13'	System	21 Jan 2021 16:57:17
	System	21 Jan 2021 16:57:17

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-01-28T11:07:25', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'e5a0027a-a1e0-489d-a349-5fefb2b93411' User entered 'No (N)'	System	28 Jan 2021 16:07:34

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-01-28T11:07:28', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'e5a0027a-a1e0-489d-a349-5fefb2b93411' User entered 'No (N)'	System	28 Jan 2021 16:07:34

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-01-28T11:07:31', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'e5a0027a-a1e0-489d-a349-5fefb2b93411' User entered '28 Jan 2021 11:07:31'	System	28 Jan 2021 16:07:34
	System	28 Jan 2021 16:07:34

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-02-03T09:46:19', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'bd25e623-442c-4eb6-a6e6-c307ef6c38c6'	System	03 Feb 2021 14:46:32
User entered 'No (N)'	System	03 Feb 2021 14:46:32

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-02-03T09:46:24', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'bd25e623-442c-4eb6-a6e6-c307ef6c38c6'	System	03 Feb 2021 14:46:32
User entered 'No (N)'	System	03 Feb 2021 14:46:32

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-02-03T09:46:27', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'bd25e623-442c-4eb6-a6e6-c307ef6c38c6'	System	03 Feb 2021 14:46:32
User entered '03 Feb 2021 09:46:27'	System	03 Feb 2021 14:46:32

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-02-10T09:33:10', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '70cc6305-49c6-4a40-bdef-933c044b287b' User entered 'No (N)'	System	10 Feb 2021 14:33:21
	System	10 Feb 2021 14:33:21

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-02-10T09:33:13', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '70cc6305-49c6-4a40-bdef-933c044b287b' User entered 'No (N)'	System	10 Feb 2021 14:33:21

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-02-10T09:33:18', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '70cc6305-49c6-4a40-bdef-933c044b287b' User entered '10 Feb 2021 09:33:18'	System	10 Feb 2021 14:33:21
	System	10 Feb 2021 14:33:21

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-02-17T18:50:53', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '32791636-75e5-4c79-a134-54311fee718'	System	17 Feb 2021 23:51:04
User entered 'No (N)'	System	17 Feb 2021 23:51:04

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-02-17T18:50:56', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '32791636-75e5-4c79-a134-54311fee718'	System	17 Feb 2021 23:51:04
User entered 'No (N)'	System	17 Feb 2021 23:51:04

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-02-17T18:50:59', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '32791636-75e5-4c79-a134-54311fee718'	System	17 Feb 2021 23:51:04
User entered '17 Feb 2021 18:50:59'	System	17 Feb 2021 23:51:04

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-02-26T10:32:09-05:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'a8a8cefb-2b42-4d5b-b88c-119ad31d528a' User entered 'No (N)'	System	26 Feb 2021 15:32:19
	System	26 Feb 2021 15:32:19

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-02-26T10:32:11-05:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'a8a8cefb-2b42-4d5b-b88c-119ad31d528a' User entered 'No (N)'	System	26 Feb 2021 15:32:19
	System	26 Feb 2021 15:32:19

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-02-26T10:32:13-05:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'a8a8cefb-2b42-4d5b-b88c-119ad31d528a' User entered '26 Feb 2021 15:32:13'	System	26 Feb 2021 15:32:19
	System	26 Feb 2021 15:32:19

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-03-03T22:49:06-05:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'dfa9e3f4-d0a5-4690-aa4e-b53dc085ef25'	System	04 Mar 2021 03:51:09
User entered 'No (N)'	System	04 Mar 2021 03:51:09

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-03-03T22:49:11-05:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'dfa9e3f4-d0a5-4690-aa4e-b53dc085ef25'	System	04 Mar 2021 03:51:09
User entered 'No (N)'	System	04 Mar 2021 03:51:09

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-03-03T22:49:13-05:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'dfa9e3f4-d0a5-4690-aa4e-b53dc085ef25'	System	04 Mar 2021 03:51:09
User entered '03 Mar 2021 22:49:13'	System	04 Mar 2021 03:51:09

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-03-10T08:54:08-05:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '9d103eb3-056d-4b85-a5fe-5080a1029e36'	System	10 Mar 2021 13:54:18
User entered 'No (N)'	System	10 Mar 2021 13:54:18

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-03-10T08:54:12-05:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '9d103eb3-056d-4b85-a5fe-5080a1029e36'	System	10 Mar 2021 13:54:18
User entered 'No (N)'	System	10 Mar 2021 13:54:18

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-03-10T08:54:15-05:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '9d103eb3-056d-4b85-a5fe-5080a1029e36'	System	10 Mar 2021 13:54:18
User entered '10 Mar 2021 08:54:15'	System	10 Mar 2021 13:54:18

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-03-21T11:59:24-04:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '0587bb37-c4c5-4200-8803-190c3c731e82'	System	21 Mar 2021 15:59:34
User entered 'No (N)'	System	21 Mar 2021 15:59:34

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-03-21T11:59:26-04:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '0587bb37-c4c5-4200-8803-190c3c731e82'	System	21 Mar 2021 15:59:34
User entered 'No (N)'	System	21 Mar 2021 15:59:34

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-03-21T11:59:30-04:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '0587bb37-c4c5-4200-8803-190c3c731e82'	System	21 Mar 2021 15:59:34
User entered '21 Mar 2021 11:59:30'	System	21 Mar 2021 15:59:34

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-03-26T10:58:49-04:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'fb32b7a7-22f5-4eda-bd91-9ac8dcf71a75'	System	26 Mar 2021 14:58:56
User entered 'No (N)'	System	26 Mar 2021 14:58:56

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-03-26T10:58:51-04:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'fb32b7a7-22f5-4eda-bd91-9ac8dcf71a75'	System	26 Mar 2021 14:58:56
User entered 'No (N)'	System	26 Mar 2021 14:58:56

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-03-26T10:58:53-04:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'fb32b7a7-22f5-4eda-bd91-9ac8dcf71a75'	System	26 Mar 2021 14:58:56
User entered '26 Mar 2021 10:58:53'	System	26 Mar 2021 14:58:56

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-04-02T12:06:58-05:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'f5aa040a-85af-4a35-b2ca-a49ed17f7d09'	System	02 Apr 2021 17:10:02
User entered 'No (N)'	System	02 Apr 2021 17:10:02

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-04-02T12:07:03-05:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'f5aa040a-85af-4a35-b2ca-a49ed17f7d09'	System	02 Apr 2021 17:10:02
User entered 'No (N)'	System	02 Apr 2021 17:10:02

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-04-02T12:07:05-05:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'f5aa040a-85af-4a35-b2ca-a49ed17f7d09'	System	02 Apr 2021 17:10:02
User entered '02 Apr 2021 12:07:05'	System	02 Apr 2021 17:10:02

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-04-08T08:51:39-04:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '6618b336-a930-478f-be63-cb3736cd0a8f' User entered 'No (N)'	System	08 Apr 2021 12:51:48

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-04-08T08:51:42-04:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '6618b336-a930-478f-be63-cb3736cd0a8f'	System	08 Apr 2021 12:51:48
User entered 'No (N)'	System	08 Apr 2021 12:51:48

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-04-08T08:51:44-04:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '6618b336-a930-478f-be63-cb3736cd0a8f' User entered '08 Apr 2021 08:51:44'	System	08 Apr 2021 12:51:48
	System	08 Apr 2021 12:51:48

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-04-14T07:56:03-04:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '408c9098-12cc-4b60-bfac-c899dc45dee5'	System	14 Apr 2021 11:56:12
User entered 'No (N)'	System	14 Apr 2021 11:56:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-04-14T07:56:06-04:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '408c9098-12cc-4b60-bfac-c899dc45dee5'	System	14 Apr 2021 11:56:12
User entered 'No (N)'	System	14 Apr 2021 11:56:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-04-14T07:56:10-04:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '408c9098-12cc-4b60-bfac-c899dc45dee5'	System	14 Apr 2021 11:56:12
User entered '14 Apr 2021 07:56:10'	System	14 Apr 2021 11:56:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-04-21T19:51:49-04:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '6893273c-4627-45a7-bb1e-b20428651497'	System	21 Apr 2021 23:51:58
User entered 'No (N)'	System	21 Apr 2021 23:51:58

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-04-21T19:51:52-04:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '6893273c-4627-45a7-bb1e-b20428651497'	System	21 Apr 2021 23:51:58
User entered 'No (N)'	System	21 Apr 2021 23:51:58

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-04-21T19:51:54-04:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '6893273c-4627-45a7-bb1e-b20428651497'	System	21 Apr 2021 23:51:58
User entered '21 Apr 2021 19:51:54'	System	21 Apr 2021 23:51:58

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-05-01T23:11:32-04:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '2376f07b-0fb2-43cd-90a6-879ff88774d3'	System	02 May 2021 03:11:42
User entered 'No (N)'	System	02 May 2021 03:11:42

US3542108

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-05-01T23:11:37-04:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '2376f07b-0fb2-43cd-90a6-879ff88774d3'	System	02 May 2021 03:11:42
User entered 'No (N)'	System	02 May 2021 03:11:42

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-05-01T23:11:40-04:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: '2376f07b-0fb2-43cd-90a6-879ff88774d3'	System	02 May 2021 03:11:42
User entered '01 May 2021 23:11:40'	System	02 May 2021 03:11:42

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 21:10:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 21:10:12

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 21:10:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 21:10:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 21:10:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 21:10:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '26 Oct 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '30 Oct 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '02 Nov 2022 00:01'	System	19 Nov 2020 21:10:12

US3542108

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:10:12
Amendment Manager: User entered '06 Nov 2022 23:59'	System	19 Nov 2020 21:10:12

US3542108

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:06:32

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-03-02T16:51:33-05:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'a0d2b1e9-fc79-4ad6-b8e6-a40c9e4a22f0'	System	02 Mar 2021 21:51:55
User entered 'Yes (Y)'	System	02 Mar 2021 21:51:55

US3542108

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:06:32

Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-03-02T16:51:40-05:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'a0d2b1e9-fc79-4ad6-b8e6-a40c9e4a22f0'	System	02 Mar 2021 21:51:55
User entered 'No (N)'	System	02 Mar 2021 21:51:55

US3542108

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:06:32

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEFD7E69-0052-49F8-9474-F072DF8D485A)', Time: '2021-03-02T16:51:42-05:00', User OID: 'PatientReportedOutcome (US3542108)', ODM File OID: 'a0d2b1e9-fc79-4ad6-b8e6-a40c9e4a22f0'	System	02 Mar 2021 21:51:55
User entered '02 Mar 2021 16:51:42'	System	02 Mar 2021 21:51:55

US3542108

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:57:25
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	30 Nov 2020 18:51:40

US3542108

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:57:25
User entered '24 Nov 2020'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	30 Nov 2020 18:51:40

US3542108

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:57:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	30 Nov 2020 18:51:40

US3542108

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4)	01 Dec 2020 16:57:25
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	30 Nov 2020 18:51:40
	(b) (4)	

US3542108

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User signature succeeded.	David Diemert (u) (4)	01 Dec 2020 16:57:25
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	30 Nov 2020 18:51:44
	(b) (4)	

US3542108

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:09:50
User entered 'l'	System	30 Nov 2020 18:51:44

US3542108

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User signature succeeded.	David Diemert (b) (4)	08 Jan 2021 03:22:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:20:07

US3542108

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User signature succeeded.	David Diemert (b) (4)	08 Jan 2021 03:22:12
User entered '29 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:20:07

US3542108

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User signature succeeded.	David Diemert (b) (4)	08 Jan 2021 03:22:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Jan 2021 21:20:07

US3542108

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User signature succeeded.	David Diemert (b) (4)	08 Jan 2021 03:22:12
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:20:07

US3542108

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User signature succeeded.	David Diemert (b) (4)	08 Jan 2021 03:22:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:19:57

US3542108

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User entered 'l'	System	04 Jan 2021 21:19:57

US3542108

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:19:25
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	27 Jan 2021 18:34:44

US3542108

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:19:25
User entered '26 Jan 2021'	(b) (4) Taylor Ladson (b) (4)	27 Jan 2021 18:34:44

US3542108

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:19:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Taylor Ladson (b) (4)	27 Jan 2021 18:34:44

US3542108

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:19:25
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	27 Jan 2021 18:34:44

US3542108

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:19:25
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	27 Jan 2021 18:34:32

US3542108

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User entered 'l'	System	27 Jan 2021 18:34:32

US3542108

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User signature succeeded.	David Diemert (b) (4)	23 Feb 2021 20:11:37
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	23 Feb 2021 17:58:35

US3542108

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User signature succeeded.	David Diemert (b) (4)	23 Feb 2021 20:11:37
User entered '23 Feb 2021'	(b) (4) Taylor Ladson (b) (4) (b) (4)	23 Feb 2021 17:58:35

US3542108

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User signature succeeded.	David Diemert (b) (4)	23 Feb 2021 20:11:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Taylor Ladson (b) (4)	23 Feb 2021 17:58:35

US3542108

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User signature succeeded.	David Diemert (b) (4)	23 Feb 2021 20:11:37
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	23 Feb 2021 17:58:35

US3542108

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User signature succeeded.	David Diemert (b) (4)	23 Feb 2021 20:11:37
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	23 Feb 2021 17:58:23

US3542108

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User entered 'l'	System	23 Feb 2021 17:58:23

US3542108

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User signature succeeded.	David Diemert (b) (4)	26 Mar 2021 16:51:53
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	25 Mar 2021 17:54:01

US3542108

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User signature succeeded.	David Diemert (b) (4)	26 Mar 2021 16:51:53
User entered '25 Mar 2021'	(b) (4) Erika Faust (b) (4)	25 Mar 2021 17:54:01

US3542108

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:32

[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 10:01:57
User signature succeeded.	David Diemert (b) (4)	26 Mar 2021 16:51:53
User entered 'Clinic (Clinic)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 17:54:01

US3542108

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User entered 'VISIT4'	System	25 Mar 2021 17:54:01

US3542108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:16:03
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	31 Mar 2021 18:02:02
	(b) (4)	

US3542108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:16:03
User entered empty.	(b) (4) Taylor Ladson (b) (4)	31 Mar 2021 18:02:02
	(b) (4)	

US3542108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:16:03
User entered empty.	(b) (4) Taylor Ladson (b) (4)	31 Mar 2021 18:02:02
	(b) (4)	

US3542108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User entered empty.	System	31 Mar 2021 18:02:02

US3542108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:16:03
User entered empty.	(b) (4) Taylor Ladson (b) (4)	31 Mar 2021 18:02:02
	(b) (4)	

US3542108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:16:03
User entered empty.	(b) (4) Taylor Ladson (b) (4)	31 Mar 2021 18:02:02
	(b) (4)	

US3542108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:16:03
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	31 Mar 2021 18:02:02

US3542108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:16:03
User entered empty.	(b) (4) Taylor Ladson (b) (4)	31 Mar 2021 18:02:02
	(b) (4)	

US3542108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User entered empty.	System	31 Mar 2021 18:02:02

US3542108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:16:03
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	31 Mar 2021 18:02:02

US3542108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User entered empty.	System	31 Mar 2021 18:02:02

US3542108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:16:03
User entered empty.	(b) (4) Taylor Ladson (b) (4)	31 Mar 2021 18:02:02
	(b) (4)	

US3542108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User entered empty.	System	31 Mar 2021 18:02:02

US3542108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:16:03
User entered empty.	(b) (4) Taylor Ladson (b) (4)	31 Mar 2021 18:02:02
	(b) (4)	

US3542108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User entered empty.	System	31 Mar 2021 18:02:02

US3542108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57

US3542108

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:32

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57

US3542108

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:06:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User signature succeeded.	David Diemert (b) (4)	26 Mar 2021 16:51:53
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 17:54:05

US3542108

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:06:32

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User signature succeeded.	David Diemert (b) (4)	26 Mar 2021 16:51:53
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 17:54:05

US3542108

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User signature succeeded.	David Diemert (b) (4)	26 Mar 2021 16:51:53
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 17:54:17

US3542108

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User signature succeeded.	David Diemert (b) (4)	26 Mar 2021 16:51:53
User entered '25 Mar 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 17:54:17

US3542108

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:32

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User signature succeeded.	David Diemert (b) (4)	26 Mar 2021 16:51:53
User entered '10:28'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 17:54:17

US3542108

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User entered '25 Mar 2021 10:28'	System	25 Mar 2021 17:54:17

US3542108

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User signature succeeded.	David Diemert (b) (4)	26 Mar 2021 16:51:53
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	25 Mar 2021 17:54:24

US3542108

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:01:57
User entered 'I'	System	25 Mar 2021 17:54:24

US3542108

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

Form: Visit Date

Generated On: 10 Jun 2021 08:06:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:34:05
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	03 Feb 2021 17:08:51

US3542108

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

Form: Visit Date

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:34:05
User entered '02 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	03 Feb 2021 17:08:51

US3542108

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

Form: Visit Date

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:34:05
User entered 'Clinic (Clinic)'	(b) (4) Erika Faust (b) (4) (b) (4)	03 Feb 2021 17:08:51

US3542108

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

Form: Visit Date

Generated On: 10 Jun 2021 08:06:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered 'UNBLND_DECIDE'	System	03 Feb 2021 17:08:51

US3542108

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

Form: Unblinding

Generated On: 10 Jun 2021 08:06:32

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:34:05
User entered '02 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	03 Feb 2021 17:09:19

US3542108

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

Form: Unblinding

Generated On: 10 Jun 2021 08:06:32

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:43:00
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:39:57

US3542108

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

Form: Unblinding

Generated On: 10 Jun 2021 08:06:32

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:34:05
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	03 Feb 2021 17:09:19

US3542108

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

Form: Unblinding

Generated On: 10 Jun 2021 08:06:32

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:43:00
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 07:39:57

US3542108

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

Form: Unblinding

Generated On: 10 Jun 2021 08:06:32

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:34:05
User entered '02 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	03 Feb 2021 17:09:19

US3542108

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

Form: Unblinding

Generated On: 10 Jun 2021 08:06:32

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:34:05
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Erika Faust (b) (4) (b) (4)	03 Feb 2021 17:09:19

US3542108

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

Form: Unblinding

Generated On: 10 Jun 2021 08:06:32

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:34:05
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Erika Faust (b) (4) (b) (4)	03 Feb 2021 17:09:19

US3542108

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

Form: Unblinding

Generated On: 10 Jun 2021 08:06:32

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:34:05
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Erika Faust (b) (4) (b) (4)	03 Feb 2021 17:09:19

US3542108

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

Form: Unblinding

Generated On: 10 Jun 2021 08:06:32

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:34:05
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	03 Feb 2021 17:09:19

US3542108

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

Form: Unblinding

Generated On: 10 Jun 2021 08:06:32

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered empty.	System	03 Feb 2021 17:09:19

US3542108

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

Form: Unblinding

Generated On: 10 Jun 2021 08:06:32

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered empty.	System	03 Feb 2021 17:09:19

US3542108

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:34:05
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	03 Feb 2021 17:09:36

US3542108

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:34:05
User entered '02 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	03 Feb 2021 17:09:36

US3542108

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:32

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:34:05
User entered '11:16'	(b) (4) Erika Faust (b) (4) (b) (4)	03 Feb 2021 17:09:36

US3542108

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered '02 Feb 2021 11:16'	System	03 Feb 2021 17:09:36

US3542108

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:06:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:34:05
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	03 Feb 2021 17:09:47

US3542108

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:06:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:34:05
User entered '02 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	03 Feb 2021 17:09:47

US3542108

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:06:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:34:05
User entered '11:20'	(b) (4) Erika Faust (b) (4) (b) (4)	03 Feb 2021 17:09:47

US3542108

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:06:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:45:26
User entered '02 Feb 2021 11:20'	System	03 Feb 2021 17:09:47

US3542108

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:06:32

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:01
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:31:16
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	07 Oct 2020 17:31:17

US3542108

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:32

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:07:39
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
User entered 'USA-US084-2020-mRNA-1273-P301000003'	(b) (4) System	06 Nov 2020 16:57:17
User entered 'New'	(b) (4), (b) (6)	06 Nov 2020 16:57:17

US3542108

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:32

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:01:44
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Swelling face, LLT: Cheek swelling - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 05:33:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 05:33:17
User signature succeeded.	David Diemert (b) (4) (b) (4)	08 Oct 2020 03:01:20
Data point term sent to Coder	System	07 Oct 2020 17:32:03
User entered 'Cheek swelling, bilateral'	Hannah Yellin (b) (4) (b) (4)	07 Oct 2020 17:32:01

US3542108

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:01:49
User signature succeeded.	David Diemert (b) (4)	05 Nov 2020 17:15:28
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	05 Nov 2020 16:40:19
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	David Diemert (b) (4)	05 Nov 2020 16:40:19
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
	(b) (4)	
User entered 'No (N)'	Hannah Yellin (b) (4)	07 Oct 2020 17:32:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:01:51
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	07 Oct 2020 17:32:01

US3542108

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:01:52
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	07 Oct 2020 17:32:01

US3542108

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:01:57
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered '30 Sep 2020'	(b) (4) Hannah Yellin (b) (4) (b) (4)	07 Oct 2020 17:32:01

US3542108

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:02:17
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered '10:00'	(b) (4) Hannah Yellin (b) (4) (b) (4)	07 Oct 2020 17:32:01

US3542108

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 10:00'	System	07 Oct 2020 17:32:01

US3542108

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:32

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:02:30
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	07 Oct 2020 17:32:01

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:02:20
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered '05 Oct 2020'	(b) (4) Hannah Yellin (b) (4) (b) (4)	07 Oct 2020 17:32:01

US3542108

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:32

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:02:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 12:40:29
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
Query 'Data is required. Please provide.' answered with 'End date not within 24 hours of dosing' (Site from System).	(b) (4)	
	Hannah Yellin (b) (4)	07 Oct 2020 17:32:31
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 17:32:01
User entered empty.	Hannah Yellin (b) (4)	07 Oct 2020 17:32:01
	(b) (4)	

US3542108

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 17:32:01

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:02:25
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Hannah Yellin (b) (4)	07 Oct 2020 17:32:01

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Folder: Adverse Events

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:02:27
User signature succeeded.	David Diemert (b) (4)	05 Nov 2020 17:15:28
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	05 Nov 2020 16:46:15
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	05 Nov 2020 16:40:19
Signature has been broken.	David Diemert (b) (4) (b) (4)	05 Nov 2020 16:40:19
User entered 'Yes (Y)' reason for change: New Information	David Diemert (b) (4) (b) (4)	05 Nov 2020 16:40:19
User signature succeeded.	David Diemert (b) (4) (b) (4)	08 Oct 2020 03:01:20
User entered 'No (N)'	Hannah Yellin (b) (4) (b) (4)	07 Oct 2020 17:32:01

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:03:24
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	07 Oct 2020 17:32:01

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:03:22
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	07 Oct 2020 17:32:01

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:03:21
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	07 Oct 2020 17:32:01

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:03:18
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	07 Oct 2020 17:32:01

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Folder: Adverse Events

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:03:16
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	07 Oct 2020 17:32:01

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:03:11
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	07 Oct 2020 17:32:01

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:03:09
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	07 Oct 2020 17:32:01

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:03:06
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	07 Oct 2020 17:32:01

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:02:52
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	07 Oct 2020 17:32:01

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:02:51
User signature succeeded.	David Diemert (b) (4)	05 Nov 2020 17:15:28
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	05 Nov 2020 16:46:15
	(b) (4)	
User entered '1' reason for change: New Information	David Diemert (b) (4)	05 Nov 2020 16:46:15
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
	(b) (4)	
User entered '0'	Hannah Yellin (b) (4)	07 Oct 2020 17:32:01
	(b) (4)	

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:02:46
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered 'Related (RELATED)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	07 Oct 2020 17:32:01

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:02:43
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered 'Not Related (NOT RELATED)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	07 Oct 2020 17:32:01

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:32

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:57:25
User closed query 'PV Query: As the last dose of study drug was given on 29 Sep 2020. please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	21 Nov 2020 17:45:25
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:49:18
Query 'PV Query: As the last dose of study drug was given on 29 Sep 2020. please update the action taken with study drug from none to not applicable.' answered with 'Updated to not applicable' (Site from Safety).	Hannah Yellin (b) (4) (b) (4)	19 Nov 2020 17:31:22
DataPoint Un-verified.	Hannah Yellin (b) (4) (b) (4)	19 Nov 2020 17:31:12
Signature has been broken.	Hannah Yellin (b) (4) (b) (4)	19 Nov 2020 17:31:12
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	Hannah Yellin (b) (4) (b) (4)	19 Nov 2020 17:31:12
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:07:39
User opened query 'PV Query: As the last dose of study drug was given on 29 Sep 2020. please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 21:08:01
User signature succeeded.	David Diemert (b) (4) (b) (4)	08 Oct 2020 03:01:20
User entered 'None (NONE)'	Hannah Yellin (b) (4) (b) (4)	07 Oct 2020 17:32:01

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:03:38
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	07 Oct 2020 17:32:01

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:03:34
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered 'l'	(b) (4) Hannah Yellin (b) (4) (b) (4)	07 Oct 2020 17:32:01

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:03:36
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	07 Oct 2020 17:32:01

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:03:43
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Hannah Yellin (b) (4)	07 Oct 2020 17:32:01

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Folder: Adverse Events

Form: Adverse Events (1)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:03:41
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	07 Oct 2020 17:32:01

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = HAD BILATERAL VOLUMA CHEEK INJECTIONS IN MARCH 2020 (FIRST AND ONLY ADMINISTRATION). However, this is not recorded in the Med History eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 09:17:51
User closed query 'Per DM CLR: SAE Narrative = SOLUMEDROL DOSE PACK (4MG TABS) ON 03OCT2020 (THROUGH 07OCT2020). However, in CM eCRF the dose is "UNKNOWN". Please review and reconcile data as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 09:16:30
Query 'Per DM CLR: SAE Narrative = SOLUMEDROL DOSE PACK (4MG TABS) ON 03OCT2020 (THROUGH 07OCT2020). However, in CM eCRF the dose is "UNKNOWN". Please review and reconcile data as appropriate.' answered with 'Medrol Pak dosing is a taper. Con Med eCRF updated.' (Site from DM).	David Diemert (b) (4) (b) (4)	22 Dec 2020 22:17:44
Query 'Per DM CLR: SAE Narrative = HAD BILATERAL VOLUMA CHEEK INJECTIONS IN MARCH 2020 (FIRST AND ONLY ADMINISTRATION). However, this is not recorded in the Med History eCRF. Please review and ensure that this is captured in the appropriate eCRF.' answered with 'Added to MH eCRF.' (Site from DM).	David Diemert (b) (4) (b) (4)	22 Dec 2020 22:03:31
User opened query 'Per DM CLR: SAE Narrative = SOLUMEDROL DOSE PACK (4MG TABS) ON 03OCT2020 (THROUGH 07OCT2020). However, in CM eCRF the dose is "UNKNOWN". Please review and reconcile data as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 06:17:36
User opened query 'Per DM CLR: SAE Narrative = HAD BILATERAL VOLUMA CHEEK INJECTIONS IN MARCH 2020 (FIRST AND ONLY ADMINISTRATION). However, this is not recorded in the Med History eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 06:17:31
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:07:39
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Nov 2020 17:15:28

PRODUCTION RELEASE (v12.003
EAB) (1725)

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[Narrative](#)

Audit	User	Time (GMT)
User entered '46 YEAR OLD FEMALE ENROLLED AND RECEIVED 1ST DOSE OF VACCINE/PLACEBO ON 31AUG2020; 2ND DOSE ADMINISTERED ON 29SEP2020. STARTING NIGHT OF 29SEP2020 HAD INJECTION SITE PAIN, THROUGH 30SEP2020. ALSO MODERATE MYALGIAS & ARTHRALGIAS 30SEP-01OCT2020. AWOKE 30SEP2020 WITH SIGNIFICANT BILATERAL CHEEK SWELLING; NO RASH, PAIN, TENDERNESS, ORAL OR RESPIRATORY SYMPTOMS. NO FEVER/CHILLS. FELT ABSOLUTELY WELL ASIDE FROM UNSIGHTLY CHEEK SWELLING. NO NEW MEDS, FOODS, CREAMS, TOOTHPASTE, ETC. OF NOTE, HAD BILATERAL VOLUMA CHEEK INJECTIONS IN MARCH 2020 (FIRST AND ONLY ADMINISTRATION), WITHOUT INCIDENT. NO RELIEF FROM BENADRYL (50MG QD 01-03OCT2020). DUE TO ONGOING SWELLING, STARTED ON SOLUMEDROL DOSE PACK (4MG TABS) ON 03OCT2020 (THROUGH 07OCT2020). CONSIDERABLY IMPROVED BY 04OCT2020 WITH COMPLETE RESOLUTION OF SWELLING BY 05OCT2020. NO RECURRENCE. WAS NOT ORIGINALLY REPORTED AS AN SAE BUT DUE TO RECENT MEDWATCH REPORT (MOD-2020-000515, participant US3322329) of a very similar event in another study participant post-Voluma filler injection, I am now submitting this event as an unexpected, related SAE (in my clinical judgement).' <p>reason for change: New Information</p>	David Diemert (b) (4)	05 Nov 2020 16:56:52

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[Narrative](#)

Audit	User	Time (GMT)
User entered '46 YEAR OLD FEMALE ENROLLED AND RECEIVED 1ST DOSE OF VACCINE/PLACEBO ON 31AUG2020; 2ND DOSE ADMINISTERED ON 29SEP2020. STARTING NIGHT OF 29SEP2020 HAD INJECTION SITE PAIN, THROUGH 30SEP2020. ALSO MODERATE MYALGIAS & ARTHRALGIAS 30SEP-01OCT2020. AWOKE 30SEP2020 WITH SIGNIFICANT BILATERAL cheek swelling; no rash, pain, tenderness, oral or respiratory symptoms. No fever/chills. Felt absolutely well aside from unsightly cheek swelling. No new meds, foods, creams, toothpaste, etc. Of note, had bilateral Voluma cheek injections in March 2020 (first and only administration), without incident. No relief from Benadryl (50mg QD 01-03OCT2020). Due to ongoing swelling, started on Solumedrol dose pack (5mg tabs) on 03OCT2020 (through 07OCT2020). Considerably improved by 04OCT2020 with complete resolution of swelling by 05OCT2020. No recurrence. Was not originally reported as SAE but due (b) (6) reason for change: Data Entry Error	David Diemert (b) (4) (b) (4)	05 Nov 2020 16:53:12
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	05 Nov 2020 16:46:15
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	05 Nov 2020 16:46:15
Signature has been broken.	David Diemert (b) (4) (b) (4)	05 Nov 2020 16:46:15
User entered '46 year old female enrolled and received 1st dose of vaccine/placebo on 31AUG2020; 2nd dose administered on 29SEP2020. Starting night of 29SEP2020 had injection site pain, through 30SEP2020. Also moderate myalgias & arthralgias 30SEP-01OCT2020. Awoke 30SEP2020 with significant bilateral' reason for change: Data Entry Error	David Diemert (b) (4) (b) (4)	05 Nov 2020 16:46:15
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	05 Nov 2020 16:40:19

PRODUCTION RELEASE (v12.003
EAB) (1725)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered empty.	(b) (4) Hannah Yellin (b) (4)	07 Oct 2020 17:32:01
	(b) (4)	

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 16:40:19
User entered '0'	System	07 Oct 2020 17:32:01

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Folder: Adverse Events

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Nov 2020 16:40:19
User entered 'O'	System	07 Oct 2020 17:32:01

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Folder: Adverse Events

Form: Adverse Events (2)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:07:39
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User coded data point as SOC: Eye disorders, HLGT: Ocular infections, irritations and inflammations, HLT: Ocular infections, inflammations and associated manifestations, PT: Eye pruritus, LLT: Eye pruritus - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 18:02:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 18:02:38
Data point term sent to Coder	System	28 Oct 2020 15:27:48
User entered 'Ocular Pruritus'	Erika Faust (b) (4)	28 Oct 2020 15:27:44

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:07:39
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:27:44

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:07:39
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:27:44

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:07:39
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:27:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:07:39
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered '17 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:27:44

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[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:07:39
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:27:44

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14
User entered empty.	System	28 Oct 2020 15:27:44

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:07:39
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:27:44

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:07:39
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered '17 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:27:44

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:07:39
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:27:44

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14
User entered empty.	System	28 Oct 2020 15:27:44

US3542108

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:32

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:07:39
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:27:44

US3542108

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:07:39
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:27:44

US3542108

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:32

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:07:39
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:27:44

US3542108

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:32

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:07:39
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:27:44

US3542108

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:07:39
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:27:44

US3542108

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:07:39
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:27:44

US3542108

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:32

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:07:39
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:27:44

US3542108

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:07:39
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:27:44

US3542108

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:07:39
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:27:44

US3542108

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:07:39
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:27:44

US3542108

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:07:39
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:27:44

US3542108

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:32

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:07:39
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:27:44

US3542108

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:07:39
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered 'Not Related (NOT RELATED)'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:27:44

US3542108

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:07:39
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered 'Not Related (NOT RELATED)'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:27:44

US3542108

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:07:39
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered 'None (NONE)'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:27:44

US3542108

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:32

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:07:39
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:27:44

US3542108

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:07:39
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered 'l'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:27:44

US3542108

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:07:39
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:27:44

US3542108

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:32

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:07:39
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:27:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:32

[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 18:12:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:07:39
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:27:44

US3542108

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:32

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:07:39
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:27:44

US3542108

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:32

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14
User entered '0'	System	28 Oct 2020 15:27:44

US3542108

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:32

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14
User entered '0'	System	28 Oct 2020 15:27:44

US3542108

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:12:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:06:32

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:01
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:08:54
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:20:19

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:32

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: DULOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: CYMBALTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 20:23:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 20:23:05
Data point term sent to Coder	System	01 Sep 2020 20:21:02
User entered 'Cymbalta'	Madhu Balachandran (b) (4)	01 Sep 2020 20:20:52

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:32

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:20:52

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:32

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'Anxiety'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:20:52

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:32

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered '60'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:20:52

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:32

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'mg (mg)'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:20:52

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:32

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:20:52

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:32

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'once daily (QD)'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:20:52

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:20:52

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:32

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'Oral (ORAL)'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:20:52

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:32

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:20:52

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
Signature has been broken.	(b) (4)	
	Hannah Yellin (b) (4)	07 Oct 2020 17:28:48
	(b) (4)	
User entered 'un UNK 2018' reason for change: New Information	Hannah Yellin (b) (4)	07 Oct 2020 17:28:48
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
	(b) (4)	
User entered empty.	Madhu Balachandran	01 Sep 2020 20:20:52
	(b) (4)	

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:32

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
Signature has been broken.	(b) (4)	
	Hannah Yellin (b) (4)	07 Oct 2020 17:28:48
	(b) (4)	
User entered '0' reason for change: New Information	Hannah Yellin (b) (4)	07 Oct 2020 17:28:48
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
	(b) (4)	
User entered '1'	Madhu Balachandran	01 Sep 2020 20:20:52
	(b) (4)	

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:32

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:20:52

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:20:52

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:37:17
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	01 Sep 2020 20:20:52

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	01 Sep 2020 20:20:52

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Sep 2020 20:20:52

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 20:20:52

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:37
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
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)	12 Oct 2020 17:31:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 17:31:24
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: ACRIVASTINE, PRODUCTSYNONYM: BENADRYL [ACRIVASTINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 22:53:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 22:53:34
Data point term sent to Coder	System	07 Oct 2020 16:45:39
User entered 'Benadryl'	Madhu Balachandran (b) (4)	07 Oct 2020 16:45:08

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:37
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	07 Oct 2020 16:45:08

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:37
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered 'Cheek Swelling'	(b) (4) Madhu Balachandran (b) (4)	07 Oct 2020 16:45:08

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:37
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered '50'	(b) (4) Madhu Balachandran (b) (4)	07 Oct 2020 16:45:08

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:37
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered 'mg (mg)'	(b) (4) Madhu Balachandran (b) (4)	07 Oct 2020 16:45:08

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:37
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	07 Oct 2020 16:45:08

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:37
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered 'once daily (QD)'	(b) (4) Madhu Balachandran (b) (4)	07 Oct 2020 16:45:08

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:37
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	07 Oct 2020 16:45:08

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:37
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered 'Oral (ORAL)'	(b) (4) Madhu Balachandran (b) (4)	07 Oct 2020 16:45:08

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:37
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	07 Oct 2020 16:45:08

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:37
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered '01 Oct 2020'	(b) (4) Madhu Balachandran (b) (4)	07 Oct 2020 16:45:08

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:37
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	07 Oct 2020 16:45:08

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:37
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	07 Oct 2020 16:45:08

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:37
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered '03 Oct 2020'	(b) (4) Madhu Balachandran (b) (4)	07 Oct 2020 16:45:08

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:37
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered 'No (N)' reason for change: New Information	Hannah Yellin (b) (4)	07 Oct 2020 17:29:20
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	07 Oct 2020 16:45:08

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:37
User entered 'I'	System	07 Oct 2020 16:45:08

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:37
User entered '1'	System	07 Oct 2020 16:45:08

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:37
User entered '804 (804)'	System	07 Oct 2020 16:45:08

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:32

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:07
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:11:11
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE SODIUM SUCCINATE, PRODUCTSYNONYM: SOLUMEDROL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Oct 2020 21:48:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Oct 2020 21:48:51
Data point term sent to Coder	System	07 Oct 2020 17:31:02
User entered 'SOLUMEDROL dose pak' reason for change: New Information	Hannah Yellin (b) (4)	07 Oct 2020 17:30:26
Data point term sent to Coder	System	07 Oct 2020 16:48:43
User entered 'Solumedrol'	Madhu Balachandran (b) (4)	07 Oct 2020 16:48:04

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:07
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:11:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	07 Oct 2020 16:48:04

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:07
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered 'Cheek swelling' reason for change: New Information	Hannah Yellin (b) (4)	07 Oct 2020 17:30:26
User entered 'Unknown'	Madhu Balachandran (b) (4)	07 Oct 2020 16:48:04

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:07
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:10:53
User signature succeeded.	David Diemert (b) (4)	22 Dec 2020 22:17:58
Signature has been broken.	David Diemert (b) (4)	22 Dec 2020 22:15:22
User entered '4' reason for change: New Information	David Diemert (b) (4)	22 Dec 2020 22:15:22
Query 'Per SAE narrative dose of this medication was 4mg. Please verify and update if needed. ' canceled (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 19:21:17
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:42
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User opened query 'Per SAE narrative dose of this medication was 4mg. Please verify and update if needed. ' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 16:10:51
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered 'un' reason for change: New Information	Hannah Yellin (b) (4)	07 Oct 2020 17:30:26
User entered '4'	Madhu Balachandran (b) (4)	07 Oct 2020 16:48:04

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:07
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:10:53
User signature succeeded.	David Diemert (b) (4)	22 Dec 2020 22:17:58
Signature has been broken.	David Diemert (b) (4)	22 Dec 2020 22:15:22
User entered 'mg (mg)' reason for change: New Information	David Diemert (b) (4)	22 Dec 2020 22:15:22
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:46
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered 'Other (OTHER)' reason for change: New Information	Hannah Yellin (b) (4)	07 Oct 2020 17:30:26
User entered 'mg (mg)'	Madhu Balachandran (b) (4)	07 Oct 2020 16:48:04

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:07
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:10:53
User signature succeeded.	David Diemert (b) (4)	22 Dec 2020 22:17:58
DataPoint Un-verified.	(b) (4) David Diemert (b) (4)	22 Dec 2020 22:15:22
Signature has been broken.	(b) (4) David Diemert (b) (4)	22 Dec 2020 22:15:22
User entered empty; reason for change New Information	(b) (4) David Diemert (b) (4)	22 Dec 2020 22:15:22
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered 'Unknown' reason for change: New Information	(b) (4) Hannah Yellin (b) (4)	07 Oct 2020 17:30:26
User entered empty.	(b) (4) Madhu Balachandran	07 Oct 2020 16:48:04
	(b) (4)	

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:07
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:10:53
User signature succeeded.	David Diemert (b) (4)	22 Dec 2020 22:17:58
DataPoint Un-verified.	David Diemert (b) (4)	22 Dec 2020 22:15:22
Signature has been broken.	David Diemert (b) (4)	22 Dec 2020 22:15:22
User entered 'other (OTHER)' reason for change: New Information	David Diemert (b) (4)	22 Dec 2020 22:15:22
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered 'once daily (QD)' reason for change: New Information	Hannah Yellin (b) (4)	07 Oct 2020 17:30:26
User entered 'unknown (UNKNOWN)'	Madhu Balachandran (b) (4)	07 Oct 2020 16:48:04

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:07
User closed query 'Please update as separate ConMed lines - Eg 5 different lines for each different dose.' (Site from CRA).	(b) (4), (b) (6)	28 Feb 2021 17:36:37
Query 'Please update as separate ConMed lines - Eg 5 different lines for each different dose.' answered with 'Seriously???? I don't even understand why dosages are being recorded. I regularly do Phase 1 vaccine trials and we don't collect dose. What is FDA going to do with this information?????' (Site from CRA).	David Diemert (b) (4)	19 Feb 2021 02:40:57
User opened query 'Please update as separate ConMed lines - Eg 5 different lines for each different dose.' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 19:16:52
DataPoint Un-verified.	(b) (4), (b) (6)	17 Feb 2021 19:16:28
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:10:53
User signature succeeded.	David Diemert (b) (4)	22 Dec 2020 22:17:58
DataPoint Un-verified.	David Diemert (b) (4)	22 Dec 2020 22:15:22
Signature has been broken.	David Diemert (b) (4)	22 Dec 2020 22:15:22
User entered '20mg on Day 1 16mg on Day 2 12mg on Day 3 8mg on Day 4 4mg on Day 5' reason for change: New Information	David Diemert (b) (4)	22 Dec 2020 22:15:22
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered empty.	Madhu Balachandran (b) (4)	07 Oct 2020 16:48:04

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:07
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered 'Oral (ORAL)'	(b) (4) Madhu Balachandran (b) (4)	07 Oct 2020 16:48:04

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:07
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	07 Oct 2020 16:48:04

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:07
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered '03 Oct 2020'	(b) (4) Madhu Balachandran (b) (4)	07 Oct 2020 16:48:04

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:07
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	07 Oct 2020 16:48:04

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:07
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 02:53:34
Signature has been broken.	(b) (4)	
	Taylor Ladson (b) (4)	14 Oct 2020 18:56:20
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Taylor Ladson (b) (4)	14 Oct 2020 18:56:20
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
	(b) (4)	
User entered 'Yes (Y)'	Madhu Balachandran	07 Oct 2020 16:48:04
	(b) (4)	

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:07
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	16 Oct 2020 02:53:34
Signature has been broken.	(b) (4)	
	Taylor Ladson (b) (4)	14 Oct 2020 18:56:20
	(b) (4)	
User entered '7 Oct 2020' reason for change: New Information	Taylor Ladson (b) (4)	14 Oct 2020 18:56:20
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
	(b) (4)	
User entered empty.	Madhu Balachandran	07 Oct 2020 16:48:04
	(b) (4)	

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:07
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered 'No (N)' reason for change: New Information	Hannah Yellin (b) (4)	07 Oct 2020 17:30:26
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	07 Oct 2020 16:48:04

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:07
User entered empty.	System	22 Dec 2020 22:15:22
User entered '1'	System	07 Oct 2020 17:30:26
User entered empty.	System	07 Oct 2020 16:48:04

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:07
User entered empty.	System	22 Dec 2020 22:15:22
User entered '1'	System	07 Oct 2020 17:30:26
User entered empty.	System	07 Oct 2020 16:48:04

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:07
User entered empty.	System	22 Dec 2020 22:15:22
User entered '804 (804)'	System	07 Oct 2020 17:30:26
User entered empty.	System	07 Oct 2020 16:48:04

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:18
User closed query 'Per CDM: Per diary dose 2 dated 04Oct2020, patient took medication to prevent pain/fever. However, there is no record in the CM page with the same date. Please confirm and update data accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 06:07:33
Query 'Per CDM: Per diary dose 2 dated 04Oct2020, patient took medication to prevent pain/fever. However, there is no record in the CM page with the same date. Please confirm and update data accordingly.' answered with 'Diary dose 2 dated 04OCT2020 was a late entry in the morning for study day 5 which is 03OCT2020. Dates for con med and diary by study day (rather than calendar date) match participant verbal reporting' (Site from DM). DataPoint Verified.	Elissa Malkin (b) (4) (b) (4)	24 Nov 2020 18:10:40
User opened query 'Per CDM: Per diary dose 2 dated 04Oct2020, patient took medication to prevent pain/fever. However, there is no record in the CM page with the same date. Please confirm and update data accordingly.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	(b) (4), (b) (6)	16 Nov 2020 13:48:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\202003.	David Diemert (b) (4) (b) (4)	08 Oct 2020 03:01:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 17:00:47
Data point term sent to Coder User entered 'Tylenol'	Coder Import (b) (4) System Madhu Balachandran (b) (4)	07 Oct 2020 17:00:47 07 Oct 2020 16:53:55 07 Oct 2020 16:53:50

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:18
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	07 Oct 2020 16:53:50

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:18
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE AND MYALGIAS are considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE AND MYALGIAS did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 13:43:30
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE AND MYALGIAS are considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE AND MYALGIAS did not meet the AE reporting criteria. ' answered with 'taken for solicited events reported in diary' (Site from DM).	Elissa Malkin (b) (4) (b) (4)	13 Nov 2020 14:35:03

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:32

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE AND MYALGIAS are considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE AND MYALGIAS did not meet the AE reporting criteria. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	12 Nov 2020 16:34:29
	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered 'Headache and Myalgias'	(b) (4) Madhu Balachandran (b) (4)	07 Oct 2020 16:53:50

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:18
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered '650' reason for change: New Information	Hannah Yellin (b) (4)	07 Oct 2020 17:30:48
User entered 'l'	Madhu Balachandran (b) (4)	07 Oct 2020 16:53:50

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:18
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered 'mg (mg)' reason for change: New Information	Hannah Yellin (b) (4)	07 Oct 2020 17:30:48
User entered 'tablet (TABLET)'	Madhu Balachandran (b) (4)	07 Oct 2020 16:53:50

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:18
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	07 Oct 2020 16:53:50

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:18
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered 'once daily (QD)'	(b) (4) Madhu Balachandran (b) (4)	07 Oct 2020 16:53:50

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:18
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	07 Oct 2020 16:53:50

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:18
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered 'Oral (ORAL)'	(b) (4) Madhu Balachandran (b) (4)	07 Oct 2020 16:53:50

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:18
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	07 Oct 2020 16:53:50

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:18
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered '30 Sep 2020'	(b) (4) Madhu Balachandran (b) (4)	07 Oct 2020 16:53:50

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:18
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	07 Oct 2020 16:53:50

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:18
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	07 Oct 2020 16:53:50

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:18
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered '03 Oct 2020' reason for change: Data Entry Error	Hannah Yellin (b) (4)	07 Oct 2020 17:30:48
User entered '3 Oct 2020'	Madhu Balachandran (b) (4)	07 Oct 2020 16:53:50

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:18
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 03:01:20
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	07 Oct 2020 16:53:50

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:18
User entered 'I'	System	07 Oct 2020 16:53:50

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:18
User entered 'I'	System	07 Oct 2020 16:53:50

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:18
User entered '804 (804)'	System	07 Oct 2020 16:53:50

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:53
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
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)	29 Oct 2020 18:03:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 18:03:35
Data point term sent to Coder	System	28 Oct 2020 15:26:45
User entered 'Benadryl'	Erika Faust (b) (4)	28 Oct 2020 15:26:34

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:53
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:26:34

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:53
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered 'Ocular Pruritus'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:26:34

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:53
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered '50'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:26:34

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:53
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered 'mg (mg)'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:26:34

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:53
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:26:34

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:53
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered 'once (ONCE)'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:26:34

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:53
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:26:34

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:53
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered 'Oral (ORAL)'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:26:34

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:53
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:26:34

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:53
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered '17 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:26:34

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:53
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:26:34

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:53
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:26:34

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:53
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered '17 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:26:34

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:53
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:13:28
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:19:07
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	28 Oct 2020 15:26:34

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:53
User entered empty.	System	28 Oct 2020 15:26:34

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:53
User entered empty.	System	28 Oct 2020 15:26:34

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:53
User entered empty.	System	28 Oct 2020 15:26:34

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:00
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:10:53
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:57:25
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Nov 2020 18:57:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Nov 2020 18:57:10
Data point term sent to Coder	System	30 Nov 2020 18:56:04
User entered 'influenza vaccination'	DeEnna Wedding (b) (4)	30 Nov 2020 18:55:28

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:00
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:10:53
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:57:25
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	30 Nov 2020 18:55:28

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:00
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:10:53
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:57:25
User entered 'influenza prevention'	(b) (4) DeEnna Wedding (b) (4)	30 Nov 2020 18:55:28

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:00
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:10:53
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:57:25
User entered '0.5'	(b) (4) DeEnna Wedding (b) (4)	30 Nov 2020 18:55:28

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:00
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:10:53
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:57:25
User entered 'mL (mL)'	(b) (4) DeEnna Wedding (b) (4)	30 Nov 2020 18:55:28

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:00
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:10:53
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:57:25
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	30 Nov 2020 18:55:28

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:00
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:10:53
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:57:25
User entered 'once (ONCE)'	(b) (4) DeEnna Wedding (b) (4)	30 Nov 2020 18:55:28

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:00
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:10:53
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:57:25
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	30 Nov 2020 18:55:28

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:00
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:10:53
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:57:25
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) DeEnna Wedding (b) (4)	30 Nov 2020 18:55:28

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:00
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:10:53
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:57:25
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	30 Nov 2020 18:55:28

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:00
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:10:53
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:57:25
User entered '26 Oct 2020'	(b) (4) DeEnna Wedding (b) (4)	30 Nov 2020 18:55:28

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:00
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:10:53
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:57:25
User entered '0'	(b) (4) DeEnna Wedding (b) (4)	(b) (4) 30 Nov 2020 18:55:28

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:00
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:10:53
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:57:25
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	30 Nov 2020 18:55:28

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:00
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:10:53
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:57:25
User entered '26 Oct 2020'	(b) (4) DeEnna Wedding (b) (4)	30 Nov 2020 18:55:28

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:00
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:10:53
User signature succeeded.	David Diemert (b) (4)	01 Dec 2020 16:57:25
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	30 Nov 2020 18:55:28

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:00
User entered empty.	System	30 Nov 2020 18:55:28

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:00
User entered empty.	System	30 Nov 2020 18:55:28

US3542108

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:28:00
User entered empty.	System	30 Nov 2020 18:55:28

US3542108

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:06:32

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:34:05
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	03 Feb 2021 19:40:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
Query 'Please print SAE submission form and file in subject source binder. ' canceled (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 19:21:49
User opened query 'Please print SAE submission form and file in subject source binder. ' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 16:18:20
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'USA-US084-2020-MRNA-1273-P301000003'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'Yes (Y)'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'No (N)'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'No (N)'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'No (N)'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'No (N)'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'No (N)'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'Yes (Y)'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'David'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'Diemert'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered '2300 Eye Street NW'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'Washington'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'DC'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered '20037'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 16:02:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
User entered 'US'	(b) (4) System	06 Nov 2020 16:57:36

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:52:01
Signature has been broken.	(b) (4)	
User entered '2'	System	21 Nov 2020 16:02:23
User signature succeeded.	System	21 Nov 2020 16:02:23
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
User entered '1'	(b) (4)	
	System	06 Nov 2020 16:57:36

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
Query 'Please print SAE submission form and file in subject source binder. ' canceled (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 19:21:49
User opened query 'Please print SAE submission form and file in subject source binder. ' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 16:18:20
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'USA-US084-2020-MRNA-1273-P301000003'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'Yes (Y)'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'No (N)'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'No (N)'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'No (N)'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'No (N)'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'No (N)'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'Yes (Y)'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'David'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'Diemert'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered '2300 Eye Street NW'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'Washington'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'DC'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered '20037'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 16:02:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
User entered 'US'	(b) (4) System	06 Nov 2020 16:57:36

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:52:01
Signature has been broken.	(b) (4)	
User entered '2'	System	21 Nov 2020 16:02:23
User signature succeeded.	System	21 Nov 2020 16:02:23
User entered '1'	David Diemert (b) (4)	12 Nov 2020 21:50:05
	(b) (4)	
	System	06 Nov 2020 16:57:36

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:06:32

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
User entered '06/Nov/2020 16:57'	(b) (4) System	06 Nov 2020 16:57:36

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:06:32

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 16:02:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
User entered 'l'	(b) (4), (b) (6)	06 Nov 2020 16:57:36

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
Query 'Please print SAE submission form and file in subject source binder. ' canceled (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 19:21:49
User opened query 'Please print SAE submission form and file in subject source binder. ' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 16:18:20
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'USA-US084-2020-MRNA-1273-P301000003'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'Yes (Y)'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'No (N)'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'No (N)'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'No (N)'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'No (N)'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'No (N)'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'Yes (Y)'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'David'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'Diemert'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered '2300 Eye Street NW'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'Washington'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered 'DC'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:57:29
User entered '20037'	System	06 Nov 2020 16:57:17

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 16:02:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:57
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:50:05
User entered 'US'	(b) (4) System	06 Nov 2020 16:57:36

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:52:01
Signature has been broken.	(b) (4)	
User entered '2'	System	21 Nov 2020 16:02:23
User signature succeeded.	System	21 Nov 2020 16:02:23
	David Diemert (b) (4)	12 Nov 2020 21:50:05
	(b) (4)	
User entered '1'	System	06 Nov 2020 16:57:36

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:06:32

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:52:01
User entered '21/Nov/2020 16:02'	(b) (4) System	21 Nov 2020 16:02:23

US3542108

Folder: SAE USA-US084-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:06:32

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:52:01
User entered 'I'	(b) (4) (b) (4), (b) (6)	21 Nov 2020 16:02:23