

US3122090 (Prod: M3 Wake Research, Inc - M3 Wake)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:23:12

All time stamps listed in this document are displayed in GMT

US3122090

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 20:57:14

Generated On: 09 Jun 2021 15:23:12

[Participant ID](#)

US3122090

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

US3122090

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:57:37

Generated On: 09 Jun 2021 15:23:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 JUL 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

US3122090

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 20:57:37

Generated On: 09 Jun 2021 15:23:12

Date of Birth (MMM yyyy)	(b) (6) 1958
Age	62
Age Units	YEARS
Age (Derived)	62
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input 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

US3122090

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 20:57:37

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Date of Informed Consent (*dd MMM yyyy*) 29 JUL 2020

Month and Year of Informed Consent (derived) JUL 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input checked="" type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify _____

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number _____

Enrollment Trigger 1

US3122090

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 20:57:37

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 20:57:37

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 20:57:37

Generated On: 09 Jun 2021 15:23:12

Condition	MIGRAINES
Start date (dd MMM yyyy)	UN UNK 1968
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 1968
Start Year (derived)	1968
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 20:57:37

Generated On: 09 Jun 2021 15:23:12

Condition	ROSACEA
Start date (dd MMM yyyy)	(b) (6) 1958
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	(b) (6) 1958
Start Year (derived)	1958
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 20:57:37

Generated On: 09 Jun 2021 15:23:12

Condition	FINGER REPAIR SURGERY - RIGHT INDEX, DUE TO PARTIAL SEVERAGE
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2000
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2000
Stop Year (derived)	2000

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 20:57:37

Generated On: 09 Jun 2021 15:23:12

Condition	RIGHT INDEX FINGER PARTIALLY SEVERED
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2000
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2000
Stop Year (derived)	2000

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 20:57:40

Generated On: 09 Jun 2021 15:23:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 JUL 2020
Time of assessment (00:00-23:59)	08:52 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 08:52
Height (xxx.x)	64 in
Weight (xxx.x)	207 lb
BMI (xxx.x)	35.60576 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	ND - Not Done
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) 19 Feb 2021 20:57:37

Generated On: 09 Jun 2021 15:23:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 JUL 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) 19 Feb 2021 20:57:37

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Date of assessment (*dd MMM yyyy*) 29 JUL 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 2010

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 20:57:37

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 20:57:37

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:57:40

Generated On: 09 Jun 2021 15:23:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 JUL 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) 19 Feb 2021 20:57:40

Generated On: 09 Jun 2021 15:23:12

What was the date of randomization? (dd MMM yyyy) 29 JUL 2020

What was the participant's randomization number? 100106

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 20:57:40

Generated On: 09 Jun 2021 15:23:12

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) 19 Feb 2021 20:57:40

Generated On: 09 Jun 2021 15:23:12

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)	29 JUL 2020
Time of assessment (00:00-23:59)	08:52 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 08:52
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 20:57:40

Generated On: 09 Jun 2021 15:23:12

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)	29 JUL 2020
Time of assessment (00:00-23:59)	08:52 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 08:52
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:57:40

Generated On: 09 Jun 2021 15:23:12

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.

US3122090

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 20:57:40

Generated On: 09 Jun 2021 15:23:12

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 JUL 2020

What was the treatment time? (00:00-23:59) 10:35 (24 HR)

Treatment Date and Time (derived) 29 JUL 2020 10:35

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) 19 Feb 2021 20:57:40

Generated On: 09 Jun 2021 15:23:12

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 JUL 2020
Collection time (00:00-23:59)	09:45 (24 HR)
Collection date and time (derived)	29 JUL 2020 09:45

US3122090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 20:57:40

Generated On: 09 Jun 2021 15:23:12

Collection date (dd MMM yyyy)			29 JUL 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:50	29 JUL 2020 09:50
Nasopharyngeal Swab 2	No		

US3122090

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:57:40

Generated On: 09 Jun 2021 15:23:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

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

97.4 °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 JUL 2020 10:59

PC Open Date & Time

29 JUL 2020 10:55

PC Close Date & Time

29 JUL 2020 13:25

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

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 98.4 °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 JUL 2020 16:21
PC Open Date & Time	29 JUL 2020 14:20
PC Close Date & Time	30 JUL 2020 11:59

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:23:12

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

97.8 °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

30 JUL 2020 12:02

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 JUL 2020 12:02

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 AUG 2020 12:35

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:23:12

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

97.5 °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

02 AUG 2020 16:37

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:23:12

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

97.7 °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

03 AUG 2020 16:56

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:23:12

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

97.8 °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 AUG 2020 17:45

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 JUL 2020 11:00

PC Open Date & Time

29 JUL 2020 10:55

PC Close Date & Time

29 JUL 2020 13:25

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

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 JUL 2020 16:22

PC Open Date & Time

29 JUL 2020 14:20

PC Close Date & Time

30 JUL 2020 11:59

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:12

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 JUL 2020 12:02

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:12

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

31 JUL 2020 12:03

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:12

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

01 AUG 2020 12:35

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:12

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

02 AUG 2020 16:37

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:12

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

03 AUG 2020 16:56

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:12

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

04 AUG 2020 17:45

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

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 ☐

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

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

No ☒

Yes ☐

PC Time stamp	29 JUL 2020 11:01
PC Open Date & Time	29 JUL 2020 10:55
PC Close Date & Time	29 JUL 2020 13:25

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

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 ☐

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

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

No ☒

Yes ☐

PC Time stamp	29 JUL 2020 16:22
PC Open Date & Time	29 JUL 2020 14:20
PC Close Date & Time	30 JUL 2020 11:59

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:12

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 ☒

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:12

Yes <input type="checkbox"/>	
PC Time stamp	30 JUL 2020 12:03
PC Open Date & Time	30 JUL 2020 12:00
PC Close Date & Time	31 JUL 2020 11:59

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:12

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)

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:12

Yes <input type="checkbox"/>	
PC Time stamp	31 JUL 2020 12:03
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:12

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 ☒

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:12

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 12:36
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:12

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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EAB) (1725)

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US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:12

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 16:38
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:12

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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EAB) (1725)

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US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:12

Yes <input type="checkbox"/>	
PC Time stamp	03 AUG 2020 16:57
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:12

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 ☒

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:12

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 17:46
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3122090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:23:12

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	05 AUG 2020 12:18
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3122090

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:57:15

Generated On: 09 Jun 2021 15:23:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122090

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:57:15

Generated On: 09 Jun 2021 15:23:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122090

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:57:15

Generated On: 09 Jun 2021 15:23:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122090

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:57:15

Generated On: 09 Jun 2021 15:23:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122090

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:57:15

Generated On: 09 Jun 2021 15:23:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122090

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:57:15

Generated On: 09 Jun 2021 15:23:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122090

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:57:40

Generated On: 09 Jun 2021 15:23:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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	VISIT2

US3122090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 20:57:40

Generated On: 09 Jun 2021 15:23:12

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)	26 AUG 2020
Time of assessment (00:00-23:59)	11:46 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 11:46
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3122090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 20:57:40

Generated On: 09 Jun 2021 15:23:12

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	14:15 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 14:15
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3122090

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:57:40

Generated On: 09 Jun 2021 15:23:12

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.

US3122090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 20:57:40

Generated On: 09 Jun 2021 15:23:12

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) 26 AUG 2020

What was the treatment time? (00:00-23:59) 13:31 (24 HR)

Treatment Date and Time (derived) 26 AUG 2020 13:31

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

US3122090

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 20:57:40

Generated On: 09 Jun 2021 15:23:12

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

Collection date (dd MMM yyyy)	26 AUG 2020
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Collection time (00:00-23:59)	12:39 (24 HR)
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Collection date and time (derived)	26 AUG 2020 12:39
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US3122090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 20:57:40

Generated On: 09 Jun 2021 15:23:12

Collection date (dd MMM yyyy)			26 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:50	26 AUG 2020 12:50
Nasopharyngeal Swab 2	No		

US3122090

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:57:40

Generated On: 09 Jun 2021 15:23:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 13:52

PC Open Date & Time

26 AUG 2020 13:51

PC Close Date & Time

26 AUG 2020 16:21

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

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

97.8 °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	26 AUG 2020 17:27
PC Open Date & Time	26 AUG 2020 17:16
PC Close Date & Time	27 AUG 2020 11:59

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:23:12

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

96.5 °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

27 AUG 2020 14:03

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:23:12

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

97.8 °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

28 AUG 2020 13:33

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 16:56

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:23:12

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 16:17

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 15:29

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:23:12

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

02 SEP 2020 01:22

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 13:53

PC Open Date & Time

26 AUG 2020 13:51

PC Close Date & Time

26 AUG 2020 16:21

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

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

26 AUG 2020 17:27

PC Open Date & Time

26 AUG 2020 17:16

PC Close Date & Time

27 AUG 2020 11:59

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:12

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

27 AUG 2020 14:03

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:12

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

28 AUG 2020 13:33

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:12

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

29 AUG 2020 16:57

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:12

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

30 AUG 2020 16:18

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:12

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

31 AUG 2020 15:29

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:12

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

02 SEP 2020 01:23

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

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 ☐

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 13:54
PC Open Date & Time	26 AUG 2020 13:51
PC Close Date & Time	26 AUG 2020 16:21

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

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 ☐

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 17:27
PC Open Date & Time	26 AUG 2020 17:16
PC Close Date & Time	27 AUG 2020 11:59

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:12

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 ☒

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:12

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 14:04
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:12

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)

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:12

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 13:34
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:12

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 ☒

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:12

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 16:57
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:12

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 ☒

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:12

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 16:19
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:12

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: 09 Jun 2021 15:23:12

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 15:30
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:12

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 01:24
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3122090

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:57:15

Generated On: 09 Jun 2021 15:23:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122090

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:57:15

Generated On: 09 Jun 2021 15:23:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122090

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:57:15

Generated On: 09 Jun 2021 15:23:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122090

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:57:15

Generated On: 09 Jun 2021 15:23:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122090

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:57:15

Generated On: 09 Jun 2021 15:23:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122090

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:57:15

Generated On: 09 Jun 2021 15:23:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122090

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:57:40

Generated On: 09 Jun 2021 15:23:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 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	VISIT3

US3122090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 20:57:40

Generated On: 09 Jun 2021 15:23:12

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) _____

US3122090

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:57:40

Generated On: 09 Jun 2021 15:23:12

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.

US3122090

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 20:57:40

Generated On: 09 Jun 2021 15:23:12

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 SEP 2020

Collection time (00:00-23:59)

09:25 (24 HR)

Collection date and time (derived)

30 SEP 2020 09:25

US3122090

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:57:40

Generated On: 09 Jun 2021 15:23:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-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 SEP 2020 14:43:54

Patient Cloud Open Date & Time

28 SEP 2020 00:01

Patient Cloud Close Date & Time

02 OCT 2020 23:59

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 OCT 2020 04:09:06

Patient Cloud Open Date & Time

05 OCT 2020 00:01

Patient Cloud Close Date & Time

09 OCT 2020 23:59

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 OCT 2020 00:32:19

Patient Cloud Open Date & Time

12 OCT 2020 00:01

Patient Cloud Close Date & Time

16 OCT 2020 23:59

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 OCT 2020 03:32:20

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 NOV 2020 18:50:31

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 NOV 2020 03:30:43

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 113

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 00:15:30

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 117

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	27 NOV 2020 18:42:23
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	04 DEC 2020 08:57:44
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

12 DEC 2020 16:18:06

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" 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)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	18 DEC 2020 06:35:46
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

25 DEC 2020 00:02:13

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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 <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 JAN 2021 03:27:32
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

08 JAN 2021 04:51:37

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

15 JAN 2021 08:11:42

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

26 JAN 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 JAN 2021 06:07:32

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 FEB 2021 11:50:00
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

16 FEB 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	20 FEB 2021 08:53:33
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	26 FEB 2021 14:31:04
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

09 MAR 2021 11:37:45

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

12 MAR 2021 13:12:27

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 MAR 2021 10:00:23
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

28 MAR 2021 11:02:15

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 13:38:36

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 APR 2021 09:57:35
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 09:52:43

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 APR 2021 00:01
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Patient Cloud Close Date & Time	27 APR 2021 23:59
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US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 278

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 08:35:16

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 292

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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"/>

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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 ☐

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 313

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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"/>

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 327

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 334

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 355

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2021 00:01
Patient Cloud Close Date & Time	20 JUL 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 362

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2021 00:01
Patient Cloud Close Date & Time	27 JUL 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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°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 ☐

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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 ☐

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	13 AUG 2021 00:01
Patient Cloud Close Date & Time	17 AUG 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	24 AUG 2021 23:59
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US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 411

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 418

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 425

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 432

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	05 OCT 2021 23:59
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US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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"/>

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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 ☐

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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"/>

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 467

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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 ☐

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 481

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

Date and time of submission	
Patient Cloud Open Date & Time	19 NOV 2021 00:01
Patient Cloud Close Date & Time	23 NOV 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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"/>

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 DEC 2021 00:01
Patient Cloud Close Date & Time	07 DEC 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 502

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

Date and time of submission	
Patient Cloud Open Date & Time	10 DEC 2021 00:01
Patient Cloud Close Date & Time	14 DEC 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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 ☐

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

Date and time of submission	
Patient Cloud Open Date & Time	17 DEC 2021 00:01
Patient Cloud Close Date & Time	21 DEC 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
Patient Cloud Close Date & Time	28 DEC 2021 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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"/>

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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 ☐

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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 ☐

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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 ☐

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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 ☐

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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 ☐

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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 ☐

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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 ☐

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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 ☐

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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"/>

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 607

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 MAR 2022 00:01
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Patient Cloud Close Date & Time	29 MAR 2022 23:59
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US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 635

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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"/>

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

255 of 2135

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 656

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 663

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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"/>

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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°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 ☐

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 684

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 705

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 712

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 JUL 2022 00:01
Patient Cloud Close Date & Time	12 JUL 2022 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2022 00:01
Patient Cloud Close Date & Time	19 JUL 2022 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 733

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 740

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 747

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

Date and time of submission

Patient Cloud Open Date & Time	12 AUG 2022 00:01
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Patient Cloud Close Date & Time	16 AUG 2022 23:59
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US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

Date and time of submission

Patient Cloud Open Date & Time	19 AUG 2022 00:01
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Patient Cloud Close Date & Time	23 AUG 2022 23:59
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US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 761

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	30 AUG 2022 23:59
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US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 768

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 782

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

DAY 796

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3122090

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:23:12

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		02 MAR 2021 08:16:04

US3122090

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:57:37

Generated On: 09 Jun 2021 15:23:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122090

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:57:37

Generated On: 09 Jun 2021 15:23:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122090

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:57:15

Generated On: 09 Jun 2021 15:23:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122090

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:57:15

Generated On: 09 Jun 2021 15:23:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122090

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:57:15

Generated On: 09 Jun 2021 15:23:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122090

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:57:15

Generated On: 09 Jun 2021 15:23:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122090

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Mar 2021 19:43:11

Generated On: 09 Jun 2021 15:23:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122090

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:57:15

Generated On: 09 Jun 2021 15:23:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122090

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Mar 2021 19:43:11

Generated On: 09 Jun 2021 15:23:12

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

Visit date (dd MMM yyyy)	10 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3122090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Mar 2021 13:55:02

Generated On: 09 Jun 2021 15:23:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 FEB 2021
Time of assessment (00:00-23:59)	08:55 (24 HR)
Vital Signs Date and Time (derived)	10 FEB 2021 08:55
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3122090

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Mar 2021 19:43:11

Generated On: 09 Jun 2021 15:23:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 FEB 2021

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

US3122090

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Mar 2021 19:43:11

Generated On: 09 Jun 2021 15:23:12

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3122090

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Mar 2021 19:43:11

Generated On: 09 Jun 2021 15:23:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122090

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 24 Mar 2021 18:31:14

Generated On: 09 Jun 2021 15:23:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122090

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 24 Mar 2021 18:31:14

Generated On: 09 Jun 2021 15:23:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122090

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 14:11:27

Generated On: 09 Jun 2021 15:23:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122090

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 14:11:27

Generated On: 09 Jun 2021 15:23:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122090

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

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

US3122090

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3122090

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:23:12

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

US3122090

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:23:12

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3122090

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:57:15

Generated On: 09 Jun 2021 15:23:12

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

Visit date (dd MMM yyyy)	12 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3122090

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

Form: Unblinding

Data signed: (b) (4) 09 Apr 2021 18:47:58

Generated On: 09 Jun 2021 15:23:12

Date of updated informed consent (<i>dd MMM yyyy</i>)	12 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	12 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3122090

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 20:57:15

Generated On: 09 Jun 2021 15:23:12

Height	
Weight	
BMI (xxx.x)	

US3122090

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 20:57:15

Generated On: 09 Jun 2021 15:23:12

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 JAN 2021
Time of assessment (00:00-23:59)	08:20 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 08:20
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)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3122090

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 20:57:15

Generated On: 09 Jun 2021 15:23:12

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 JAN 2021
Time of assessment (00:00-23:59)	10:21 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 10:21
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3122090

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

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:57:15

Generated On: 09 Jun 2021 15:23:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 JAN 2021

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

US3122090

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

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 20:57:15

Generated On: 09 Jun 2021 15:23:12

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 12 JAN 2021

What was the treatment time? (00:00-23:59) 09:43 (24 HR)

Treatment Date and Time (derived) 12 JAN 2021 09:43

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

US3122090

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 20:57:15

Generated On: 09 Jun 2021 15:23:12

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00-23:59)	08:52 (24 HR)
Collection date and time (derived)	12 JAN 2021 08:52

US3122090

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 20:57:15

Generated On: 09 Jun 2021 15:23:12

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00 - 23:59)	08:54
Collection Date and Time (derived)	12 JAN 2021 08:54

US3122090

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

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:57:15

Generated On: 09 Jun 2021 15:23:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122090

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:57:37

Generated On: 09 Jun 2021 15:23:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122090

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:57:37

Generated On: 09 Jun 2021 15:23:12

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

US3122090

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:57:14

Generated On: 09 Jun 2021 15:23:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3122090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 20:57:14

Generated On: 09 Jun 2021 15:23:12

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 FEB 2021
Time of assessment (00:00-23:59)	08:55 (24 HR)
Vital Signs Date and Time (derived)	10 FEB 2021 08:55
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3122090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 20:57:14

Generated On: 09 Jun 2021 15:23:12

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)	10 FEB 2021
Time of assessment (00:00-23:59)	10:38 (24 HR)
Vital Signs Date and Time (derived)	10 FEB 2021 10:38
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 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)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3122090

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:57:14

Generated On: 09 Jun 2021 15:23:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 FEB 2021

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

US3122090

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 20:57:14

Generated On: 09 Jun 2021 15:23:12

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 10 FEB 2021

What was the treatment time? (00:00-23:59) 10:05 (24 HR)

Treatment Date and Time (derived) 10 FEB 2021 10:05

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

What was the frequency of the study treatment dosing? ONCE

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

US3122090

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:57:14

Generated On: 09 Jun 2021 15:23:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122090

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 18:34:36

Generated On: 09 Jun 2021 15:23:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122090

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 18:34:36

Generated On: 09 Jun 2021 15:23:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122090

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Mar 2021 19:18:02

Generated On: 09 Jun 2021 15:23:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3122090

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Mar 2021 19:18:02

Generated On: 09 Jun 2021 15:23:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	23 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	07:55 (24 HR)
Vital Signs Date and Time (derived)	23 MAR 2021 07:55
Temperature (<i>xxx.x</i>)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	70 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3122090

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Mar 2021 19:18:02

Generated On: 09 Jun 2021 15:23:12

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.

US3122090

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Mar 2021 19:18:02

Generated On: 09 Jun 2021 15:23:12

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 MAR 2021

Collection time (00:00-23:59)

08:04 (24 HR)

Collection date and time (derived)

23 MAR 2021 08:04

US3122090

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Apr 2021 13:16:07

Generated On: 09 Jun 2021 15:23:12

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 14:11:27

Generated On: 09 Jun 2021 15:23:12

AEID

Adverse event

ALTERED SENSE OF SMELL

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)

15 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

1 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 14:11:27

Generated On: 09 Jun 2021 15:23:12

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

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 14:11:27

Generated On: 09 Jun 2021 15:23:12

AEID

Adverse event

HEADACHES

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)

2 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)

4 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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 14:11:27

Generated On: 09 Jun 2021 15:23:12

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:	
<hr/>	
Narrative	
<hr/>	
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)	

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 14:11:27

Generated On: 09 Jun 2021 15:23:12

AEID	
Adverse event	STRESS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	2 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	4 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 type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 14:11:27

Generated On: 09 Jun 2021 15:23:12

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

US3122090

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Apr 2021 14:11:27

Generated On: 09 Jun 2021 15:23:12

AEID	USA-US063-2021-MRNA-1273-P30 1000002
Adverse event	SUBACROMIAL BURSTITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	10 FEB 2021
Start time (00:00-23:59)	17:00 (24 HR)
AE start date and time (derived)	10 FEB 2021 17:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	20 APR 2021
End time (00:00-23:59)	00:00 (24 HR)
AE End Date and Time (derived)	20 APR 2021 00:00
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3122090

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Apr 2021 14:11:27

Generated On: 09 Jun 2021 15:23:12

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

US3122090

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Apr 2021 14:11:27

Generated On: 09 Jun 2021 15:23:12

PATIENT PRESENTED FOR
EVALUATION OF LEFT
SHOULDER. REPORTED
DISCOMFORT 9 DAYS AFTER
RECEIVING 2ND COVID
VACCINE. DESCRIBED PAIN OF
THE LATERAL ANTERIOR
ASPECT OF LEFT SHOULDER.
INITIALLY SYMPTOMS WERE
SEVERE AND PREVENTING
ANY COMFORTABLE MOTION.
HER SYMPTOMS STARTED
GRADUALLY IMPROVE BY
19FEB2021. PHYSICAL EXAM
WAS DONE AT ORTHO DOCTOR
AND THERE ASSESSMENT WAS
SUBACROMIAL BURSITIS OF
THE LEFT SHOULDER. SHE WAS
COUNSELED ABOUT
CONSERVATIVE CARE AND
WILL CONTINUE ACTIVITY
MODIFICATION.

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)	

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 20:57:14

Generated On: 09 Jun 2021 15:23:12

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

Yes ☒

No ☐

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

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 19:28:39

Generated On: 09 Jun 2021 15:23:12

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication MIGRAINE

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 19:28:39

Generated On: 09 Jun 2021 15:23:12

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN JUN 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"/>

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 19:28:39

Generated On: 09 Jun 2021 15:23:12

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication MIGRAINE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 19:28:39

Generated On: 09 Jun 2021 15:23:12

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

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 19:28:39

Generated On: 09 Jun 2021 15:23:12

Name of Medication MAGNESIUM

Prophylaxis Yes ☐
No ☒

Indication GENERAL HEALTH

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 19:28:39

Generated On: 09 Jun 2021 15:23:12

	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 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 19:28:39

Generated On: 09 Jun 2021 15:23:12

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE PAIN

Dose per administration 250

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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US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 19:28:39

Generated On: 09 Jun 2021 15:23:12

	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)		12 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 12 JAN 2021		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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"/>

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 19:28:39

Generated On: 09 Jun 2021 15:23:12

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication ARM PAIN

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 19:28:39

Generated On: 09 Jun 2021 15:23:12

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 FEB 2021
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 checked="" type="radio"/>
	No	<input type="radio"/>
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"/>

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 19:28:39

Generated On: 09 Jun 2021 15:23:12

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication ARM PAIN (SIRVA)

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 19:28:39

Generated On: 09 Jun 2021 15:23:12

	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)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3122090

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Mar 2021 17:23:06

Generated On: 09 Jun 2021 15:23:12

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3122090

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:23:12

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

US3122090

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:23:12

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 ☐

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 16:57:10

Generated On: 09 Jun 2021 15:23:12

SAEID	USA-US063-2021-MRNA-1273-P301000002
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 checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	WAYNE
Investigator's Last Name	HARPER
Site Address: Street	3100 DURALEIGH RD
Site Address: City	RALEIGH
Site Address: State	NC
Site Address: Postal Code	27612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 16:57:10

Generated On: 09 Jun 2021 15:23:12

SAEID	USA-US063-2021-MRNA-1273-P301000002
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 checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	WAYNE
Investigator's Last Name	HARPER
Site Address: Street	3100 DURALEIGH RD
Site Address: City	RALEIGH
Site Address: State	NC
Site Address: Postal Code	27612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	07/APR/2021 14:43
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

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 16:57:10

Generated On: 09 Jun 2021 15:23:12

SAEID	USA-US063-2021-MRNA-1273-P301000002
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 checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	WAYNE
Investigator's Last Name	HARPER
Site Address: Street	3100 DURALEIGH RD
Site Address: City	RALEIGH
Site Address: State	NC
Site Address: Postal Code	27612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	13/APR/2021 12:14
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 16:57:10

Generated On: 09 Jun 2021 15:23:12

SAEID	USA-US063-2021-MRNA-1273-P301000002
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 checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	WAYNE
Investigator's Last Name	HARPER
Site Address: Street	3100 DURALEIGH RD
Site Address: City	RALEIGH
Site Address: State	NC
Site Address: Postal Code	27612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	15/APR/2021 11:19
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

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 16:57:10

Generated On: 09 Jun 2021 15:23:12

SAEID	USA-US063-2021-MRNA-1273-P301000002
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 checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	WAYNE
Investigator's Last Name	HARPER
Site Address: Street	3100 DURALEIGH RD
Site Address: City	RALEIGH
Site Address: State	NC
Site Address: Postal Code	27612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	26/APR/2021 12:03
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

US3122090 (Prod: M3 Wake Research, Inc - M3 Wake)

US3122090

Form: Participant Creation

Generated On: 09 Jun 2021 15:23:12

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'US3122090'	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	29 Jul 2020 13:09:12

US3122090

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:23:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:08:17

US3122090

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:23:12

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '29 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	29 Jul 2020 13:09:12

US3122090

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Clinic (Clinic)'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:08:17

US3122090

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:23:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User entered 'SCRN'	System	29 Jul 2020 14:08:17

US3122090

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:23:12

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered (b) (6) 1958'	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	29 Jul 2020 13:09:13

US3122090

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:23:12

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '62'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:08:46

US3122090

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:23:12

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User entered 'YEARS'	System	29 Jul 2020 14:08:46

US3122090

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:23:12

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User entered '62'	System	29 Jul 2020 14:09:03

US3122090

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:23:12

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Female (F)'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:08:46

US3122090

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:23:12

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:08:46

US3122090

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:23:12

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'I'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:08:46

US3122090

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:23:12

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '0'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:08:46

US3122090

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:23:12

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '0'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:08:46

US3122090

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:23:12

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '0'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:08:46

US3122090

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:23:12

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '0'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:08:46

US3122090

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:23:12

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '0'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:08:46

US3122090

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:23:12

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered empty.	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:08:46

US3122090

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:23:12

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '0'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:08:46

US3122090

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:23:12

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '0'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:08:46

US3122090

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:23:12

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '29 Jul 2020'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:09:03

US3122090

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User entered 'Jul 2020'	System	29 Jul 2020 14:09:03

US3122090

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User entered '2020'	System	29 Jul 2020 14:09:03

US3122090

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:23:12

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Amendment 1 (1)'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:09:03

US3122090

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:09:03

US3122090

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:23:12

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered empty.	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:09:03

US3122090

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:23:12

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered empty.	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:09:03

US3122090

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:23:12

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:09:03

US3122090

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:23:12

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	29 Jul 2020 13:09:12

US3122090

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:23:12

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User entered 'I'	System	29 Jul 2020 14:09:09

US3122090

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:09:09

US3122090

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:23:12

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	13 Aug 2020 15:49:05

US3122090

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:23:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 15:51:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 15:51:28
Data point term sent to Coder	System	13 Aug 2020 15:50:26
User entered 'Migraines'	Leah Corts (b) (4)	13 Aug 2020 15:49:38

US3122090

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'UN UNK 1968'	(b) (4) Leah Corts (b) (4)	13 Aug 2020 15:49:38

US3122090

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:23:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '0'	(b) (4) Leah Corts (b) (4)	13 Aug 2020 15:49:38

US3122090

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:23:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	13 Aug 2020 15:49:38

US3122090

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered empty.	(b) (4) Leah Corts (b) (4)	13 Aug 2020 15:49:38

US3122090

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:23:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '0'	(b) (4) Leah Corts (b) (4)	13 Aug 2020 15:49:38

US3122090

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User entered 'Jan 1968'	System	13 Aug 2020 15:49:38

US3122090

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User entered '1968'	System	13 Aug 2020 15:49:38

US3122090

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User entered empty.	System	13 Aug 2020 15:49:38

US3122090

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User entered empty.	System	13 Aug 2020 15:49:38

US3122090

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:23:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Rosaceas, PT: Rosacea, LLT: Rosacea - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 15:53:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 15:53:25
Data point term sent to Coder	System	13 Aug 2020 15:51:27
User entered 'Rosacea'	Leah Cortis (b) (4)	13 Aug 2020 15:50:31

US3122090

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User closed query 'Start date is prior to Date of Birth. System Please correct.' (Site from System).	(b) (4)	13 Aug 2020 15:52:49
User entered (b) (6) 1958' reason for change: Data Entry Error	Leah Corts (b) (4)	13 Aug 2020 15:52:49
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	System	13 Aug 2020 15:50:31
User entered 'UN UNK 1958'	Leah Corts (b) (4)	13 Aug 2020 15:50:31

US3122090

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:23:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '0'	(b) (4) Leah Corts (b) (4)	13 Aug 2020 15:50:31

US3122090

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:23:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	13 Aug 2020 15:50:31

US3122090

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered empty.	(b) (4) Leah Corts (b) (4)	13 Aug 2020 15:50:31

US3122090

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:23:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '0'	(b) (4) Leah Corts (b) (4)	13 Aug 2020 15:50:31

US3122090

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User entered (b) (6) 1958'	System	13 Aug 2020 15:52:49
User entered (b) (6) 1958'	System	13 Aug 2020 15:50:31

US3122090

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User entered '1958'	System	13 Aug 2020 15:50:31

US3122090

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User entered empty.	System	13 Aug 2020 15:50:31

US3122090

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User entered empty.	System	13 Aug 2020 15:50:31

US3122090

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:23:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
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) (4), (b) (6)	10 Oct 2020 12:49:28
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Finger repair operation, LLT: Finger repair operation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 20:57:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 20:57:16
Data point term sent to Coder	System	01 Oct 2020 19:48:52
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).	Brad Killebrew (b) (4)	01 Oct 2020 19:48:34
Coding entries removed.	Brad Killebrew (b) (4)	01 Oct 2020 19:48:27
User entered 'FINGER repair SURGERY - right index, due to partial severage' reason for change: Data Entry Error	Brad Killebrew (b) (4)	01 Oct 2020 19:48:27
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 Sep 2020 06:47:47
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Limb operation, LLT: Finger operation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 08:38:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 08:38:26
Data point term sent to Coder	System	13 Aug 2020 15:51:27

US3122090

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:23:12

[Condition](#)

Audit	User	Time (GMT)
User entered 'Finger Surgery'	Leah Corts (b) (4) [REDACTED] [REDACTED]	13 Aug 2020 15:51:04

US3122090

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'UN UNK 2000'	(b) (4) Leah Corts (b) (4)	13 Aug 2020 15:51:04

US3122090

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:23:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '0'	(b) (4) Leah Corts (b) (4)	13 Aug 2020 15:51:04

US3122090

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:23:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	13 Aug 2020 15:51:04

US3122090

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User closed query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Oct 2020 12:49:50
Query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' answered with 'corrected' (Site from DM).	Brad Killebrew (b) (4)	01 Oct 2020 19:48:41
User entered 'UN UNK 2000' reason for change: Data Entry Error	Brad Killebrew (b) (4)	01 Oct 2020 19:48:27
User opened query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4), (b) (6)	05 Sep 2020 06:48:08
User entered 'UN UNK 2020'	Leah Corts (b) (4)	13 Aug 2020 15:51:04

US3122090

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:23:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '0'	(b) (4) Leah Corts (b) (4)	13 Aug 2020 15:51:04

US3122090

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User entered 'Jan 2000'	System	13 Aug 2020 15:51:04

US3122090

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User entered '2000'	System	13 Aug 2020 15:51:04

US3122090

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User entered 'Jan 2000'	System	01 Oct 2020 19:48:27
User entered 'Jan 2020'	System	13 Aug 2020 15:51:04

US3122090

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User entered '2000'	System	01 Oct 2020 19:48:27
User entered '2020'	System	13 Aug 2020 15:51:04

US3122090

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:23:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Tendon rupture, LLT: Severed tendon - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 13:29:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 13:29:28
Data point term sent to Coder	System	01 Oct 2020 19:49:53
User entered 'right index finger partially severed'	Brad Killebrew (b) (4)	01 Oct 2020 19:49:37

US3122090

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'un UNK 2000'	Brad Killebrew (b) (4)	01 Oct 2020 19:49:37

US3122090

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:23:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '0'	(b) (4) Brad Killebrew (b) (4)	01 Oct 2020 19:49:37

US3122090

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:23:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'No (N)'	(b) (4) Brad Killebrew (b) (4)	01 Oct 2020 19:49:37

US3122090

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'un UNK 2000'	(b) (4) Brad Killebrew (b) (4)	01 Oct 2020 19:49:37

US3122090

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:23:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '0'	(b) (4) Brad Killebrew (b) (4)	01 Oct 2020 19:49:37

US3122090

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User entered 'Jan 2000'	System	01 Oct 2020 19:49:37

US3122090

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User entered '2000'	System	01 Oct 2020 19:49:37

US3122090

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User entered 'Jan 2000'	System	01 Oct 2020 19:49:37

US3122090

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User entered '2000'	System	01 Oct 2020 19:49:37

US3122090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:10:45

US3122090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '29 Jul 2020'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:10:45

US3122090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '08:52'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:10:45

US3122090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User entered '29 Jul 2020 08:52'	System	29 Jul 2020 14:10:45

US3122090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '64' in	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:10:45
DataPoint set to visible.	System	29 Jul 2020 14:09:09

US3122090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '207' lb	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:10:45
DataPoint set to visible.	System	29 Jul 2020 14:09:09

US3122090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
Amendment Manager: User entered '35.60576'	System	16 Sep 2020 23:37:54
User entered '35.6'	System	29 Jul 2020 14:10:45
DataPoint set to visible.	System	29 Jul 2020 14:09:09

US3122090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User entered 'kg/m2'	System	29 Jul 2020 14:10:45
DataPoint set to visible.	System	29 Jul 2020 14:09:09

US3122090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	18 Aug 2020 13:51:12
User entered '97.9' F	Leah Corts (b) (4)	29 Jul 2020 14:10:45

US3122090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User closed query 'Per CDM: Since Temperature is ND, route of measurement is not required. Please update "Route of measurement" and "If Other, specify" fields accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Sep 2020 02:01:07
Query 'Per CDM: Since Temperature is ND, route of measurement is not required. Please update "Route of measurement" and "If Other, specify" fields accordingly.' answered with 'updated' (Site from DM).	Brad Killebrew (b) (4)	08 Sep 2020 17:18:00
User entered empty; reason for change Data Entry Error	Brad Killebrew (b) (4)	08 Sep 2020 17:17:55
User opened query 'Per CDM: Since Temperature is ND, route of measurement is not required. Please update "Route of measurement" and "If Other, specify" fields accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Sep 2020 11:11:54
User entered 'Other (Other)' reason for change: Data Entry Error	Leah Corts (b) (4)	18 Aug 2020 13:51:12
User entered 'Oral (Oral)'	Leah Corts (b) (4)	29 Jul 2020 14:10:45

US3122090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	18 Aug 2020 13:51:12
User entered empty.	Leah Corts (b) (4)	29 Jul 2020 14:10:45

US3122090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	18 Aug 2020 13:51:12
User entered '71'	Leah Corts (b) (4)	29 Jul 2020 14:10:45

US3122090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User entered 'bpm'	System	29 Jul 2020 14:10:45

US3122090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	18 Aug 2020 13:51:12
User entered '16'	Leah Corts (b) (4)	29 Jul 2020 14:10:45

US3122090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User entered 'breaths/min'	System	29 Jul 2020 14:10:45

US3122090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	18 Aug 2020 13:51:12
User entered '127'	Leah Corts (b) (4)	29 Jul 2020 14:10:45

US3122090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User entered 'mmHg'	System	29 Jul 2020 14:10:45

US3122090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	18 Aug 2020 13:51:12
User entered '82'	Leah Corts (b) (4)	29 Jul 2020 14:10:45

US3122090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User entered 'mmHg'	System	29 Jul 2020 14:10:45

US3122090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 22:09:50

US3122090

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50

US3122090

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:23:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:09:24

US3122090

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:23:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	27 Aug 2020 12:10:24
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	26 Aug 2020 19:09:35
User entered '29 Jul 2020'	Leah Corts (b) (4)	29 Jul 2020 14:09:24

US3122090

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:23:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '29 Jul 2020'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:11:28

US3122090

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:11:28

US3122090

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:11:28

US3122090

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:23:12

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered empty.	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:11:28

US3122090

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered empty.	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:11:28

US3122090

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:23:12

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '0'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:11:28

US3122090

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'UN UNK 2010'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:11:28

US3122090

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:23:12

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '0'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:11:28

US3122090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 15:22:26

US3122090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 15:22:26

US3122090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:12

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)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 15:22:26

US3122090

Folder: Screening

Form: Risk of Exposure

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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)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 15:22:26

US3122090

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 15:22:26

US3122090

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)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Yes (Y)'	Leah Corts (b) (4)	24 Aug 2020 15:22:26

US3122090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:12

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)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'No (N)'	Leah Corts (b) (4)	24 Aug 2020 15:22:26

US3122090

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 15:22:26

US3122090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:12

[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)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 15:22:26

US3122090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:12

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)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 15:22:26

US3122090

Folder: Screening

Form: Risk of Exposure

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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)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'No (N)'	Leah Corts (b) (4)	24 Aug 2020 15:22:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:12

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 15:22:26

US3122090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:12

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered empty.	(b) (4) Leah Corts (b) (4)	24 Aug 2020 15:22:26

US3122090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:12

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '0'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 15:22:26

US3122090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '0'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 15:22:26

US3122090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:12

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)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '0'	Leah Corts (b) (4)	24 Aug 2020 15:22:26

US3122090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:12

[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)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '0'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 15:22:26

US3122090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:12

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)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '0'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 15:22:26

US3122090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'I'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 15:22:26

US3122090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:12

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '0'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 15:22:26

US3122090

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:23:12

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:09:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered empty.	(b) (4) Leah Corts (b) (4)	24 Aug 2020 15:22:26

US3122090

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:23:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:11:43

US3122090

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '29 Jul 2020'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:11:43

US3122090

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:23:12

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 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Clinic (Clinic)'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:11:43

US3122090

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:23:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered 'VISIT1'	System	29 Jul 2020 14:11:43

US3122090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '29 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	29 Jul 2020 13:29:38

US3122090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 01:12:38
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:12:38
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Jul 2020 13:29:38
User entered '100106' (non-conformant).	RWS_ENDPOINT ENDPOINT(b) (4)	29 Jul 2020 13:29:38

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	29 Jul 2020 13:29:38

US3122090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:23:12

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 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'No (N)'	(b) (4)	13 Aug 2020 15:53:36
	Leah Corts (b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:23:12

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 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'No (N)'	Leah Corts (b) (4)	13 Aug 2020 15:53:36

US3122090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	13 Aug 2020 15:53:36

US3122090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:23:12

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'No (N)'	Leah Corts (b) (4)	13 Aug 2020 15:53:36

US3122090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:23:12

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	13 Aug 2020 15:53:36

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:23:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	18 Aug 2020 13:52:51
User entered '64' in	Leah Corts (b) (4)	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:23:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	18 Aug 2020 13:52:51
User entered '207' lb	Leah Corts (b) (4)	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:23:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	18 Aug 2020 13:52:51
User entered '64' in	Leah Corts (b) (4)	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:23:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	18 Aug 2020 13:52:51
User entered '207' lb	Leah Corts (b) (4)	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User accepted default value 'Pre-Dose (PREDOSE)'	Leah Corts (b) (4)	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '29 Jul 2020'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '08:52'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered '29 Jul 2020 08:52'	System	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '97.9' F	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Oral (Oral)'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered empty.	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '71'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered 'bpm'	System	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '16'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered 'breaths/min'	System	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '127'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered 'mmHg'	System	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '82'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered 'mmHg'	System	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:23:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	18 Aug 2020 13:52:51
User entered '64' in	Leah Corts (b) (4)	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:23:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	18 Aug 2020 13:52:51
User entered '207' lb	Leah Corts (b) (4)	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User accepted default value 'Post-Dose (POSTDOSE)'	Leah Corts (b) (4)	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '29 Jul 2020'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 13:58:12
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Aug 2020 13:58:12
User entered '08:52' reason for change: Data Entry Error	Leah Corts (b) (4)	21 Aug 2020 13:58:12
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Jul 2020 14:13:22
User entered empty.	Leah Corts (b) (4)	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered '29 Jul 2020 08:52'	System	21 Aug 2020 13:58:12
User entered empty.	System	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 13:58:12
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Aug 2020 13:58:12
User entered '97.9' F reason for change: Data Entry Error	Leah Corts (b) (4)	21 Aug 2020 13:58:12
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Jul 2020 14:13:22
User entered empty.	Leah Corts (b) (4)	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 13:58:12
User entered 'Oral (Oral)' reason for change: Data Entry Error	Leah Corts (b) (4)	21 Aug 2020 13:58:12
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Jul 2020 14:13:22
User entered empty.	Leah Corts (b) (4)	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered empty.	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 13:58:12
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Aug 2020 13:58:12
User entered '71' reason for change: Data Entry Error	Leah Corts (b) (4)	21 Aug 2020 13:58:12
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Jul 2020 14:13:22
User entered empty.	Leah Corts (b) (4)	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered 'bpm'	System	21 Aug 2020 13:58:12
User entered empty.	System	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 13:58:12
Query 'Data is required. Please provide.' answered by System	System	21 Aug 2020 13:58:12
data change (Site from System).		
User entered '16' reason for change: Data Entry	Leah Corts (b) (4)	21 Aug 2020 13:58:12
Error		
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Jul 2020 14:13:22
User entered empty.	Leah Corts (b) (4)	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered 'breaths/min'	System	21 Aug 2020 13:58:12
User entered empty.	System	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 13:58:12
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Aug 2020 13:58:12
User entered '127' reason for change: Data Entry Error	Leah Corts (b) (4)	21 Aug 2020 13:58:12
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Jul 2020 14:13:22
User entered empty.	Leah Corts (b) (4)	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered 'mmHg'	System	21 Aug 2020 13:58:12
User entered empty.	System	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4) (b) (4)	19 Feb 2021 20:57:40
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 13:58:12
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Aug 2020 13:58:12
User entered '82' reason for change: Data Entry Error	Leah Corts (b) (4)	21 Aug 2020 13:58:12
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Jul 2020 14:13:22
User entered empty.	Leah Corts (b) (4)	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered 'mmHg'	System	21 Aug 2020 13:58:12
User entered empty.	System	29 Jul 2020 14:13:22

US3122090

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:23:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	13 Aug 2020 15:55:05

US3122090

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:23:12

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered empty.	(b) (4) Leah Corts (b) (4)	13 Aug 2020 15:55:05

US3122090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:47:17

US3122090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered empty.	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:47:17

US3122090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

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 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered empty.	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:47:17

US3122090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered 'MRNA-1273 OR PLACEBO'	System	29 Jul 2020 14:47:17

US3122090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '29 Jul 2020'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:47:17

US3122090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '10:35'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:47:17

US3122090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered '29 Jul 2020 10:35'	System	29 Jul 2020 14:47:17

US3122090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Left Arm (LEFT ARM)'	Leah Corts (b) (4)	29 Jul 2020 14:47:17

US3122090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered 'ONCE'	System	29 Jul 2020 14:47:17

US3122090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered 'INTRAMUSCULAR'	System	29 Jul 2020 14:47:17

US3122090

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:13:39

US3122090

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '29 Jul 2020'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:13:39

US3122090

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '09:45'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:13:39

US3122090

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered '29 Jul 2020 09:45'	System	29 Jul 2020 14:13:39

US3122090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:23:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '29 Jul 2020'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:13:58

US3122090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:23:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Leah Corts (b) (4)	29 Jul 2020 14:13:58

US3122090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:23:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:13:58

US3122090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:23:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '09:50'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:13:58

US3122090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered '29 Jul 2020 09:50'	System	29 Jul 2020 14:13:58

US3122090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:23:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Leah Corts (b) (4)	29 Jul 2020 14:13:58

US3122090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:23:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	29 Jul 2020 14:13:58

US3122090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:23:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered empty.	(b) (4)	29 Jul 2020 14:13:58
	Leah Corts (b) (4)	

US3122090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered empty.	System	29 Jul 2020 14:13:58

US3122090

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	13 Aug 2020 15:55:39

US3122090

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered 'I'	System	13 Aug 2020 15:55:39

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-29T10:58:34', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'db4159af-c188-4a89-a28c-601aeb2f1cfa' User entered 'Yes (Y)'	System	29 Jul 2020 14:59:09
	System	29 Jul 2020 14:59:09

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-29T10:58:44', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'db4159af-c188-4a89-a28c-601aeb2f1cfa' User entered '97.4'	System	29 Jul 2020 14:59:09
	System	29 Jul 2020 14:59:09

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-29T10:58:49', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'db4159af-c188-4a89-a28c-601aeb2f1cfa' User entered 'No (N)'	System	29 Jul 2020 14:59:09
	System	29 Jul 2020 14:59:09

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-29T10:59:04', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'db4159af-c188-4a89-a28c-601aeb2f1cfa' User entered '29 Jul 2020 10:59'	System	29 Jul 2020 14:59:09
	System	29 Jul 2020 14:59:09

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '29 Jul 2020 10:55'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '29 Jul 2020 13:25'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-29T16:21:27', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '8a036b04-36c6-4eb0-9632-5ae79f3e8903' User entered 'Yes (Y)'	System	29 Jul 2020 20:22:00
	System	29 Jul 2020 20:22:00

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-29T16:21:43', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '8a036b04-36c6-4eb0-9632-5ae79f3e8903' User entered '98.4'	System	29 Jul 2020 20:22:00
	System	29 Jul 2020 20:22:00

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-29T16:21:48', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '8a036b04-36c6-4eb0-9632-5ae79f3e8903' User entered 'No (N)'	System	29 Jul 2020 20:22:00
	System	29 Jul 2020 20:22:00

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-29T16:21:57', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '8a036b04-36c6-4eb0-9632-5ae79f3e8903' User entered '29 Jul 2020 16:21'	System	29 Jul 2020 20:22:00
	System	29 Jul 2020 20:22:00

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '29 Jul 2020 14:20'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered 'Day 2'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:23:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-30T12:01:14', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '9a9a67e2-8e9d-4ad5-b674-fec1704b8edb' User entered 'Yes (Y)'	System	30 Jul 2020 16:02:06
	System	30 Jul 2020 16:02:06

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:23:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-30T12:01:52', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '9a9a67e2-8e9d-4ad5-b674-fec1704b8edb' User entered '97.8'	System	30 Jul 2020 16:02:06
	System	30 Jul 2020 16:02:06

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-30T12:01:57', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '9a9a67e2-8e9d-4ad5-b674-fec1704b8edb' User entered 'No (N)'	System	30 Jul 2020 16:02:06
	System	30 Jul 2020 16:02:06

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:23:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-30T12:02:04', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '9a9a67e2-8e9d-4ad5-b674-fec1704b8edb' User entered '30 Jul 2020 12:02'	System	30 Jul 2020 16:02:06
	System	30 Jul 2020 16:02:06

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered 'Day 3'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:23:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-31T12:01:58', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '9221a5b5-a623-4b8b-b066-7d6bc537ebe0' User entered 'Yes (Y)'	System	31 Jul 2020 16:02:43
	System	31 Jul 2020 16:02:43

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:23:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-31T12:02:28', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '9221a5b5-a623-4b8b-b066-7d6bc537ebe0' User entered '98.0'	System	31 Jul 2020 16:02:43
	System	31 Jul 2020 16:02:43

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-31T12:02:33', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '9221a5b5-a623-4b8b-b066-7d6bc537ebe0' User entered 'No (N)'	System	31 Jul 2020 16:02:43
	System	31 Jul 2020 16:02:43

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:23:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-31T12:02:40', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '9221a5b5-a623-4b8b-b066-7d6bc537ebe0' User entered '31 Jul 2020 12:02'	System	31 Jul 2020 16:02:43
	System	31 Jul 2020 16:02:43

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered 'Day 4'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:23:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-01T12:34:45', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '65feb869-fb49-4c9b-b6af-410b389cf220' User entered 'Yes (Y)'	System	01 Aug 2020 16:35:07
	System	01 Aug 2020 16:35:07

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:23:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-01T12:34:55', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '65feb869-fb49-4c9b-b6af-410b389cf220' User entered '98.1'	System	01 Aug 2020 16:35:07
	System	01 Aug 2020 16:35:07

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-01T12:34:59', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '65feb869-fb49-4c9b-b6af-410b389cf220'	System	01 Aug 2020 16:35:07
User entered 'No (N)'	System	01 Aug 2020 16:35:07

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:23:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-01T12:35:06', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '65feb869-fb49-4c9b-b6af-410b389cf220'	System	01 Aug 2020 16:35:07
User entered '01 Aug 2020 12:35'	System	01 Aug 2020 16:35:07

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered 'Day 5'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:23:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-02T16:34:32', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'bf155d57-586f-4cae-86e4-93a1bc71abdd' User entered 'Yes (Y)'	System	02 Aug 2020 20:37:22
	System	02 Aug 2020 20:37:22

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:23:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-02T16:37:08', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'bf155d57-586f-4cae-86e4-93a1bc71abdd' User entered '97.5'	System	02 Aug 2020 20:37:22
	System	02 Aug 2020 20:37:22

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-02T16:37:13', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'bf155d57-586f-4cae-86e4-93a1bc71abdd'	System	02 Aug 2020 20:37:22
User entered 'No (N)'	System	02 Aug 2020 20:37:22

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:23:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-02T16:37:19', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'bf155d57-586f-4cae-86e4-93a1bc71abdd' User entered '02 Aug 2020 16:37'	System	02 Aug 2020 20:37:22
	System	02 Aug 2020 20:37:22

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered 'Day 6'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:23:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-03T16:54:39', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '773d0947-ff09-4d0c-ad49-e9a8a1f1bb1c' User entered 'Yes (Y)'	System	03 Aug 2020 20:56:06
	System	03 Aug 2020 20:56:06

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:23:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-03T16:55:29', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '773d0947-ff09-4d0c-ad49-e9a8a1f1bb1c' User entered '97.7'	System	03 Aug 2020 20:56:06
	System	03 Aug 2020 20:56:06

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-03T16:55:38', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '773d0947-ff09-4d0c-ad49-e9a8a1f1bb1c'	System	03 Aug 2020 20:56:06
User entered 'No (N)'	System	03 Aug 2020 20:56:06

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:23:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-03T16:56:02', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '773d0947-ff09-4d0c-ad49-e9a8a1f1bb1c' User entered '03 Aug 2020 16:56'	System	03 Aug 2020 20:56:06
	System	03 Aug 2020 20:56:06

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered 'Day 7'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:23:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-04T17:43:53', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '89741b1f-057e-4d17-8d80-adc2d0616fbb' User entered 'Yes (Y)'	System	04 Aug 2020 21:45:11
	System	04 Aug 2020 21:45:11

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:23:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-04T17:44:50', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '89741b1f-057e-4d17-8d80-adc2d0616fbb' User entered '97.8'	System	04 Aug 2020 21:45:11
	System	04 Aug 2020 21:45:11

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-04T17:44:55', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '89741b1f-057e-4d17-8d80-adc2d0616fbb' User entered 'No (N)'	System	04 Aug 2020 21:45:11
	System	04 Aug 2020 21:45:11

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:23:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-04T17:45:07', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '89741b1f-057e-4d17-8d80-adc2d0616fbb' User entered '04 Aug 2020 17:45'	System	04 Aug 2020 21:45:11
	System	04 Aug 2020 21:45:11

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '04 Aug 2020 12:00'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-29T10:59:29', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'ae28d476-e57a-4d67-a9e8-474dca96e73a' User entered 'None (1)'	System	29 Jul 2020 15:00:26
	System	29 Jul 2020 15:00:26

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-29T10:59:46', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'ae28d476-e57a-4d67-a9e8-474dca96e73a' User entered 'No (N)'	System	29 Jul 2020 15:00:26
	System	29 Jul 2020 15:00:26

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-29T10:59:54', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'ae28d476-e57a-4d67-a9e8-474dca96e73a' User entered 'No (N)'	System	29 Jul 2020 15:00:26
	System	29 Jul 2020 15:00:26

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-29T11:00:10', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'ae28d476-e57a-4d67-a9e8-474dca96e73a' User entered 'None (1)'	System	29 Jul 2020 15:00:26
	System	29 Jul 2020 15:00:26

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-29T11:00:20', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'ae28d476-e57a-4d67-a9e8-474dca96e73a' User entered '29 Jul 2020 11:00'	System	29 Jul 2020 15:00:26
	System	29 Jul 2020 15:00:26

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '29 Jul 2020 10:55'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '29 Jul 2020 13:25'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-29T16:22:05', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '36bf3b7c-b34d-4858-b4aa-540781222538' User entered 'None (1)'	System	29 Jul 2020 20:22:23
	System	29 Jul 2020 20:22:23

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-29T16:22:09', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '36bf3b7c-b34d-4858-b4aa-540781222538' User entered 'No (N)'	System	29 Jul 2020 20:22:23
	System	29 Jul 2020 20:22:23

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-29T16:22:13', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '36bf3b7c-b34d-4858-b4aa-540781222538' User entered 'No (N)'	System	29 Jul 2020 20:22:23
	System	29 Jul 2020 20:22:23

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-29T16:22:17', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '36bf3b7c-b34d-4858-b4aa-540781222538'	System	29 Jul 2020 20:22:23
User entered 'None (1)'	System	29 Jul 2020 20:22:23

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-29T16:22:21', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '36bf3b7c-b34d-4858-b4aa-540781222538' User entered '29 Jul 2020 16:22'	System	29 Jul 2020 20:22:23
	System	29 Jul 2020 20:22:23

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '29 Jul 2020 14:20'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered 'Day 2'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-30T12:02:16', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'f608a039-d2ba-48e2-83e1-c229b0c51400'	System	30 Jul 2020 16:02:48
User entered 'None (1)'	System	30 Jul 2020 16:02:48

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-30T12:02:21', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'f608a039-d2ba-48e2-83e1-c229b0c51400' User entered 'No (N)'	System	30 Jul 2020 16:02:48
	System	30 Jul 2020 16:02:48

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-30T12:02:26', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'f608a039-d2ba-48e2-83e1-c229b0c51400' User entered 'No (N)'	System	30 Jul 2020 16:02:48
	System	30 Jul 2020 16:02:48

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-30T12:02:37', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'f608a039-d2ba-48e2-83e1-c229b0c51400' User entered 'None (1)'	System	30 Jul 2020 16:02:48
	System	30 Jul 2020 16:02:48

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-30T12:02:44', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'f608a039-d2ba-48e2-83e1-c229b0c51400' User entered '30 Jul 2020 12:02'	System	30 Jul 2020 16:02:48
	System	30 Jul 2020 16:02:48

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered 'Day 3'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-31T12:02:51', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'f350b176-2251-443e-ac76-c550415125ed' User entered 'None (1)'	System	31 Jul 2020 16:03:19
	System	31 Jul 2020 16:03:19

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-31T12:02:55', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'f350b176-2251-443e-ac76-c550415125ed' User entered 'No (N)'	System	31 Jul 2020 16:03:19
	System	31 Jul 2020 16:03:19

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-31T12:02:59', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'f350b176-2251-443e-ac76-c550415125ed' User entered 'No (N)'	System	31 Jul 2020 16:03:19
	System	31 Jul 2020 16:03:19

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-31T12:03:12', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'f350b176-2251-443e-ac76-c550415125ed' User entered 'None (1)'	System	31 Jul 2020 16:03:19
	System	31 Jul 2020 16:03:19

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-31T12:03:17', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'f350b176-2251-443e-ac76-c550415125ed' User entered '31 Jul 2020 12:03'	System	31 Jul 2020 16:03:19
	System	31 Jul 2020 16:03:19

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered 'Day 4'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-01T12:35:10', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'f3cd95fe-d1b8-413b-b74b-9c2d5d468bda' User entered 'None (1)'	System	01 Aug 2020 16:35:40
	System	01 Aug 2020 16:35:40

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-01T12:35:25', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'f3cd95fe-d1b8-413b-b74b-9c2d5d468bda' User entered 'No (N)'	System	01 Aug 2020 16:35:40
	System	01 Aug 2020 16:35:40

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-01T12:35:29', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'f3cd95fe-d1b8-413b-b74b-9c2d5d468bda' User entered 'No (N)'	System	01 Aug 2020 16:35:40
	System	01 Aug 2020 16:35:40

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-01T12:35:34', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'f3cd95fe-d1b8-413b-b74b-9c2d5d468bda' User entered 'None (1)'	System	01 Aug 2020 16:35:40
	System	01 Aug 2020 16:35:40

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-01T12:35:39', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'f3cd95fe-d1b8-413b-b74b-9c2d5d468bda' User entered '01 Aug 2020 12:35'	System	01 Aug 2020 16:35:40
	System	01 Aug 2020 16:35:40

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered 'Day 5'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-02T16:37:25', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '288d0fda-fa99-4993-b045-a4ab888e9907'	System	02 Aug 2020 20:37:48
User entered 'None (1)'	System	02 Aug 2020 20:37:48

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-02T16:37:29', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '288d0fda-fa99-4993-b045-a4ab888e9907' User entered 'No (N)'	System	02 Aug 2020 20:37:48
	System	02 Aug 2020 20:37:48

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-02T16:37:36', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '288d0fda-fa99-4993-b045-a4ab888e9907' User entered 'No (N)'	System	02 Aug 2020 20:37:48
	System	02 Aug 2020 20:37:48

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-02T16:37:40', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '288d0fda-fa99-4993-b045-a4ab888e9907' User entered 'None (1)'	System	02 Aug 2020 20:37:48
	System	02 Aug 2020 20:37:48

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-02T16:37:45', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '288d0fda-fa99-4993-b045-a4ab888e9907' User entered '02 Aug 2020 16:37'	System	02 Aug 2020 20:37:48
	System	02 Aug 2020 20:37:48

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered 'Day 6'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-03T16:56:10', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'ace7a253-b095-4228-a620-beb65c5d656e' User entered 'None (1)'	System	03 Aug 2020 20:56:37
	System	03 Aug 2020 20:56:37

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-03T16:56:16', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'ace7a253-b095-4228-a620-beb65c5d656e' User entered 'No (N)'	System	03 Aug 2020 20:56:37
	System	03 Aug 2020 20:56:37

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-03T16:56:23', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'ace7a253-b095-4228-a620-beb65c5d656e' User entered 'No (N)'	System	03 Aug 2020 20:56:37
	System	03 Aug 2020 20:56:37

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-03T16:56:29', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'ace7a253-b095-4228-a620-beb65c5d656e' User entered 'None (1)'	System	03 Aug 2020 20:56:37
	System	03 Aug 2020 20:56:37

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-03T16:56:35', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'ace7a253-b095-4228-a620-beb65c5d656e' User entered '03 Aug 2020 16:56'	System	03 Aug 2020 20:56:37
	System	03 Aug 2020 20:56:37

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered 'Day 7'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-04T17:45:12', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '2635463f-1bab-4682-b0a5-e6f9b0122709' User entered 'None (1)'	System	04 Aug 2020 21:45:33
	System	04 Aug 2020 21:45:33

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-04T17:45:16', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '2635463f-1bab-4682-b0a5-e6f9b0122709'	System	04 Aug 2020 21:45:33
User entered 'No (N)'	System	04 Aug 2020 21:45:33

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-04T17:45:19', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '2635463f-1bab-4682-b0a5-e6f9b0122709' User entered 'No (N)'	System	04 Aug 2020 21:45:33
	System	04 Aug 2020 21:45:33

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-04T17:45:23', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '2635463f-1bab-4682-b0a5-e6f9b0122709' User entered 'None (1)'	System	04 Aug 2020 21:45:33
	System	04 Aug 2020 21:45:33

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-04T17:45:28', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '2635463f-1bab-4682-b0a5-e6f9b0122709' User entered '04 Aug 2020 17:45'	System	04 Aug 2020 21:45:33
	System	04 Aug 2020 21:45:33

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '04 Aug 2020 12:00'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-29T11:00:34', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '26f01ff2-1661-42f9-aa66-d4fc12d2e85e' User entered 'None (0)'	System	29 Jul 2020 15:01:07
	System	29 Jul 2020 15:01:07

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-29T11:00:39', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '26f01ff2-1661-42f9-aa66-d4fc12d2e85e' User entered 'None (0)'	System	29 Jul 2020 15:01:07
	System	29 Jul 2020 15:01:07

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-29T11:00:43', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '26f01ff2-1661-42f9-aa66-d4fc12d2e85e' User entered 'None (0)'	System	29 Jul 2020 15:01:07
	System	29 Jul 2020 15:01:07

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-29T11:00:47', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '26f01ff2-1661-42f9-aa66-d4fc12d2e85e' User entered 'None (0)'	System	29 Jul 2020 15:01:07
	System	29 Jul 2020 15:01:07

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-29T11:00:52', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '26f01ff2-1661-42f9-aa66-d4fc12d2e85e' User entered 'None (0)'	System	29 Jul 2020 15:01:07
	System	29 Jul 2020 15:01:07

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-29T11:00:56', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '26f01ff2-1661-42f9-aa66-d4fc12d2e85e' User entered 'None (0)'	System	29 Jul 2020 15:01:07
	System	29 Jul 2020 15:01:07

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-29T11:00:59', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '26f01ff2-1661-42f9-aa66-d4fc12d2e85e' User entered 'No (N)'	System	29 Jul 2020 15:01:07
	System	29 Jul 2020 15:01:07

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-29T11:01:04', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '26f01ff2-1661-42f9-aa66-d4fc12d2e85e' User entered '29 Jul 2020 11:01'	System	29 Jul 2020 15:01:07
	System	29 Jul 2020 15:01:07

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '29 Jul 2020 10:55'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '29 Jul 2020 13:25'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-29T16:22:29', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'dcd62a89-7a47-416a-8253-223e0a6a9f96'	System	29 Jul 2020 20:22:56
User entered 'None (0)'	System	29 Jul 2020 20:22:56

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-29T16:22:33', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'dcd62a89-7a47-416a-8253-223e0a6a9f96'	System	29 Jul 2020 20:22:56
User entered 'None (0)'	System	29 Jul 2020 20:22:56

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-29T16:22:36', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'dcd62a89-7a47-416a-8253-223e0a6a9f96'	System	29 Jul 2020 20:22:56
User entered 'None (0)'	System	29 Jul 2020 20:22:56

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-29T16:22:40', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'dcd62a89-7a47-416a-8253-223e0a6a9f96'	System	29 Jul 2020 20:22:56
User entered 'None (0)'	System	29 Jul 2020 20:22:56

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-29T16:22:42', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'dcd62a89-7a47-416a-8253-223e0a6a9f96'	System	29 Jul 2020 20:22:56
User entered 'None (0)'	System	29 Jul 2020 20:22:56

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-29T16:22:46', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'dcd62a89-7a47-416a-8253-223e0a6a9f96'	System	29 Jul 2020 20:22:56
User entered 'None (0)'	System	29 Jul 2020 20:22:56

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-29T16:22:50', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'dcd62a89-7a47-416a-8253-223e0a6a9f96'	System	29 Jul 2020 20:22:56
User entered 'No (N)'	System	29 Jul 2020 20:22:56

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-29T16:22:54', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'dcd62a89-7a47-416a-8253-223e0a6a9f96' User entered '29 Jul 2020 16:22'	System	29 Jul 2020 20:22:56
	System	29 Jul 2020 20:22:56

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '29 Jul 2020 14:20'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered 'Day 2'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-30T12:02:50', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '009ae0cf-64ba-4644-8406-1024a6a79054' User entered 'None (0)'	System	30 Jul 2020 16:03:20
	System	30 Jul 2020 16:03:20

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-30T12:02:54', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '009ae0cf-64ba-4644-8406-1024a6a79054' User entered 'None (0)'	System	30 Jul 2020 16:03:20
	System	30 Jul 2020 16:03:20

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-30T12:02:58', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '009ae0cf-64ba-4644-8406-1024a6a79054' User entered 'None (0)'	System	30 Jul 2020 16:03:20
	System	30 Jul 2020 16:03:20

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-30T12:03:03', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '009ae0cf-64ba-4644-8406-1024a6a79054' User entered 'None (0)'	System	30 Jul 2020 16:03:20
	System	30 Jul 2020 16:03:20

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-30T12:03:05', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '009ae0cf-64ba-4644-8406-1024a6a79054' User entered 'None (0)'	System	30 Jul 2020 16:03:20
	System	30 Jul 2020 16:03:20

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-30T12:03:10', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '009ae0cf-64ba-4644-8406-1024a6a79054' User entered 'None (0)'	System	30 Jul 2020 16:03:20
	System	30 Jul 2020 16:03:20

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-30T12:03:14', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '009ae0cf-64ba-4644-8406-1024a6a79054' User entered 'No (N)'	System	30 Jul 2020 16:03:20
	System	30 Jul 2020 16:03:20

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-30T12:03:18', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '009ae0cf-64ba-4644-8406-1024a6a79054' User entered '30 Jul 2020 12:03'	System	30 Jul 2020 16:03:20
	System	30 Jul 2020 16:03:20

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered 'Day 3'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-31T12:03:24', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '8f70dc5f-1466-4388-9275-f0176a0d222e' User entered 'None (0)'	System	31 Jul 2020 16:03:58
	System	31 Jul 2020 16:03:58

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-31T12:03:28', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '8f70dc5f-1466-4388-9275-f0176a0d222e' User entered 'None (0)'	System	31 Jul 2020 16:03:58
	System	31 Jul 2020 16:03:58

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-31T12:03:33', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '8f70dc5f-1466-4388-9275-f0176a0d222e' User entered 'None (0)'	System	31 Jul 2020 16:03:58
	System	31 Jul 2020 16:03:58

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-31T12:03:39', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '8f70dc5f-1466-4388-9275-f0176a0d222e' User entered 'None (0)'	System	31 Jul 2020 16:03:58
	System	31 Jul 2020 16:03:58

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-31T12:03:42', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '8f70dc5f-1466-4388-9275-f0176a0d222e' User entered 'None (0)'	System	31 Jul 2020 16:03:58
	System	31 Jul 2020 16:03:58

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-31T12:03:45', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '8f70dc5f-1466-4388-9275-f0176a0d222e' User entered 'None (0)'	System	31 Jul 2020 16:03:58
	System	31 Jul 2020 16:03:58

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-31T12:03:49', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '8f70dc5f-1466-4388-9275-f0176a0d222e' User entered 'No (N)'	System	31 Jul 2020 16:03:58
	System	31 Jul 2020 16:03:58

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-07-31T12:03:53', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '8f70dc5f-1466-4388-9275-f0176a0d222e' User entered '31 Jul 2020 12:03'	System	31 Jul 2020 16:03:58
	System	31 Jul 2020 16:03:58

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered 'Day 4'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-01T12:35:43', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'f9689f20-7c58-44b2-9b4f-4b2755954903' User entered 'None (0)'	System	01 Aug 2020 16:36:17
	System	01 Aug 2020 16:36:17

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-01T12:35:46', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'f9689f20-7c58-44b2-9b4f-4b2755954903' User entered 'None (0)'	System	01 Aug 2020 16:36:17
	System	01 Aug 2020 16:36:17

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-01T12:35:49', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'f9689f20-7c58-44b2-9b4f-4b2755954903' User entered 'None (0)'	System	01 Aug 2020 16:36:17
	System	01 Aug 2020 16:36:17

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-01T12:35:52', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'f9689f20-7c58-44b2-9b4f-4b2755954903' User entered 'None (0)'	System	01 Aug 2020 16:36:17
	System	01 Aug 2020 16:36:17

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-01T12:35:56', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'f9689f20-7c58-44b2-9b4f-4b2755954903' User entered 'None (0)'	System	01 Aug 2020 16:36:17
	System	01 Aug 2020 16:36:17

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-01T12:36:04', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'f9689f20-7c58-44b2-9b4f-4b2755954903' User entered 'None (0)'	System	01 Aug 2020 16:36:17
	System	01 Aug 2020 16:36:17

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-01T12:36:09', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'f9689f20-7c58-44b2-9b4f-4b2755954903'	System	01 Aug 2020 16:36:17
User entered 'No (N)'	System	01 Aug 2020 16:36:17

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-01T12:36:14', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'f9689f20-7c58-44b2-9b4f-4b2755954903'	System	01 Aug 2020 16:36:17
User entered '01 Aug 2020 12:36'	System	01 Aug 2020 16:36:17

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered 'Day 5'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-02T16:37:55', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '690a8930-a4e0-4ebf-93da-70ee9acf7e5f' User entered 'None (0)'	System	02 Aug 2020 20:38:29
	System	02 Aug 2020 20:38:29

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-02T16:38:01', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '690a8930-a4e0-4ebf-93da-70ee9acf7e5f' User entered 'None (0)'	System	02 Aug 2020 20:38:29
	System	02 Aug 2020 20:38:29

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-02T16:38:05', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '690a8930-a4e0-4ebf-93da-70ee9acf7e5f' User entered 'None (0)'	System	02 Aug 2020 20:38:29
	System	02 Aug 2020 20:38:29

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-02T16:38:10', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '690a8930-a4e0-4ebf-93da-70ee9acf7e5f' User entered 'None (0)'	System	02 Aug 2020 20:38:29
	System	02 Aug 2020 20:38:29

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-02T16:38:13', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '690a8930-a4e0-4ebf-93da-70ee9acf7e5f' User entered 'None (0)'	System	02 Aug 2020 20:38:29
	System	02 Aug 2020 20:38:29

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-02T16:38:16', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '690a8930-a4e0-4ebf-93da-70ee9acf7e5f' User entered 'None (0)'	System	02 Aug 2020 20:38:29
	System	02 Aug 2020 20:38:29

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-02T16:38:22', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '690a8930-a4e0-4ebf-93da-70ee9acf7e5f' User entered 'No (N)'	System	02 Aug 2020 20:38:29
	System	02 Aug 2020 20:38:29

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-02T16:38:27', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '690a8930-a4e0-4ebf-93da-70ee9acf7e5f' User entered '02 Aug 2020 16:38'	System	02 Aug 2020 20:38:29
	System	02 Aug 2020 20:38:29

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered 'Day 6'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-03T16:57:07', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '417edb8a-543f-4cff-8899-08852bbf5d82'	System	03 Aug 2020 20:57:44
User entered 'No interference with activity (1)'	System	03 Aug 2020 20:57:44

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-03T16:57:11', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '417edb8a-543f-4cff-8899-08852bbf5d82'	System	03 Aug 2020 20:57:44
User entered 'None (0)'	System	03 Aug 2020 20:57:44

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-03T16:57:14', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '417edb8a-543f-4cff-8899-08852bbf5d82'	System	03 Aug 2020 20:57:44
User entered 'None (0)'	System	03 Aug 2020 20:57:44

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-03T16:57:21', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '417edb8a-543f-4cff-8899-08852bbf5d82'	System	03 Aug 2020 20:57:44
User entered 'None (0)'	System	03 Aug 2020 20:57:44

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-03T16:57:26', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '417edb8a-543f-4cff-8899-08852bbf5d82'	System	03 Aug 2020 20:57:44
User entered 'None (0)'	System	03 Aug 2020 20:57:44

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-03T16:57:31', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '417edb8a-543f-4cff-8899-08852bbf5d82'	System	03 Aug 2020 20:57:44
User entered 'None (0)'	System	03 Aug 2020 20:57:44

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-03T16:57:37', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '417edb8a-543f-4cff-8899-08852bbf5d82'	System	03 Aug 2020 20:57:44
User entered 'No (N)'	System	03 Aug 2020 20:57:44

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-03T16:57:43', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '417edb8a-543f-4cff-8899-08852bbf5d82'	System	03 Aug 2020 20:57:44
User entered '03 Aug 2020 16:57'	System	03 Aug 2020 20:57:44

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered 'Day 7'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-04T17:45:56', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'ea54a74d-51ee-4289-99bb-18dd027b6194' User entered 'None (0)'	System	04 Aug 2020 21:46:21
	System	04 Aug 2020 21:46:21

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-04T17:46:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'ea54a74d-51ee-4289-99bb-18dd027b6194' User entered 'None (0)'	System	04 Aug 2020 21:46:21
	System	04 Aug 2020 21:46:21

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-04T17:46:03', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'ea54a74d-51ee-4289-99bb-18dd027b6194' User entered 'None (0)'	System	04 Aug 2020 21:46:21
	System	04 Aug 2020 21:46:21

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-04T17:46:07', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'ea54a74d-51ee-4289-99bb-18dd027b6194' User entered 'None (0)'	System	04 Aug 2020 21:46:21
	System	04 Aug 2020 21:46:21

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-04T17:46:09', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'ea54a74d-51ee-4289-99bb-18dd027b6194' User entered 'None (0)'	System	04 Aug 2020 21:46:21
	System	04 Aug 2020 21:46:21

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-04T17:46:12', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'ea54a74d-51ee-4289-99bb-18dd027b6194' User entered 'None (0)'	System	04 Aug 2020 21:46:21
	System	04 Aug 2020 21:46:21

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-04T17:46:15', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'ea54a74d-51ee-4289-99bb-18dd027b6194'	System	04 Aug 2020 21:46:21
User entered 'No (N)'	System	04 Aug 2020 21:46:21

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-04T17:46:20', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'ea54a74d-51ee-4289-99bb-18dd027b6194'	System	04 Aug 2020 21:46:21
User entered '04 Aug 2020 17:46'	System	04 Aug 2020 21:46:21

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '04 Aug 2020 12:00'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 14:47:17

US3122090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	03 Aug 2020 20:57:44
User entered 'Day 8'	System	03 Aug 2020 20:57:44

US3122090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-05T12:18:52', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'fa441177-7c6d-4557-b534-289db5205afe' User entered 'No (N)'	System	05 Aug 2020 16:19:01
	System	05 Aug 2020 16:19:01

US3122090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:23:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-05T12:18:58', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'fa441177-7c6d-4557-b534-289db5205afe' User entered '05 Aug 2020 12:18'	System	05 Aug 2020 16:19:01
	System	05 Aug 2020 16:19:01

US3122090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 20:57:44

US3122090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 20:57:44

US3122090

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	13 Aug 2020 15:58:25

US3122090

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '06 Aug 2020'	(b) (4) Leah Corts (b) (4)	13 Aug 2020 15:58:25

US3122090

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Leah Corts (b) (4)	13 Aug 2020 15:58:25

US3122090

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered empty.	(b) (4) Leah Corts (b) (4)	13 Aug 2020 15:58:25

US3122090

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	13 Aug 2020 15:58:37

US3122090

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User entered 'I'	System	13 Aug 2020 15:58:37

US3122090

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	13 Aug 2020 15:58:58

US3122090

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '12 Aug 2020'	(b) (4) Leah Corts (b) (4)	13 Aug 2020 15:58:58

US3122090

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Leah Corts (b) (4)	13 Aug 2020 15:58:58

US3122090

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered empty.	(b) (4) Leah Corts (b) (4)	13 Aug 2020 15:58:58

US3122090

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	13 Aug 2020 15:59:03

US3122090

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User entered 'I'	System	13 Aug 2020 15:59:03

US3122090

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4)	
	Aubrey Farrray (b) (4)	21 Aug 2020 17:22:47
	(b) (4)	

US3122090

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '20 Aug 2020'	(b) (4) Aubrey Farray (b) (4) (b) (4)	21 Aug 2020 17:22:47

US3122090

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Aubrey Farray (b) (4)	21 Aug 2020 17:22:47

US3122090

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered empty.	(b) (4) Aubrey Farray (b) (4)	21 Aug 2020 17:22:47

US3122090

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4) Aubrey Farrah (b) (4)	21 Aug 2020 17:22:51

US3122090

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User entered 'I'	System	21 Aug 2020 17:22:51

US3122090

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Yes (Y)'	(b) (4) Aubrey Farrey (b) (4)	26 Aug 2020 19:09:35

US3122090

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:12

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '26 Aug 2020'	(b) (4) Aubrey Farray (b) (4)	26 Aug 2020 19:09:35

US3122090

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:12

[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 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Clinic (Clinic)'	(b) (4) Aubrey Farrey (b) (4)	26 Aug 2020 19:09:35

US3122090

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered 'VISIT2'	System	26 Aug 2020 19:09:35

US3122090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User accepted default value 'Pre-Dose (PREDOSE)'	Aubrey Farray (b) (4) (b) (4)	26 Aug 2020 19:13:10

US3122090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Yes (Y)'	(b) (4) Aubrey Farrey (b) (4)	26 Aug 2020 19:13:10

US3122090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '26 Aug 2020'	(b) (4) Aubrey Farrey (b) (4)	26 Aug 2020 19:13:10

US3122090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '11:46'	(b) (4) Aubrey Farrey (b) (4) (b) (4)	26 Aug 2020 19:13:10

US3122090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered '26 Aug 2020 11:46'	System	26 Aug 2020 19:13:10

US3122090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '98.1' F	Aubrey Farray (b) (4)	26 Aug 2020 19:13:10

US3122090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Oral (Oral)'	(b) (4) Aubrey Farray (b) (4) (b) (4)	26 Aug 2020 19:13:10

US3122090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered empty.	(b) (4) Aubrey Farray (b) (4)	26 Aug 2020 19:13:10

US3122090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '67'	(b) (4) Aubrey Farray (b) (4) (b) (4)	26 Aug 2020 19:13:10

US3122090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered 'bpm'	System	26 Aug 2020 19:13:10

US3122090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '15'	(b) (4) Aubrey Farray (b) (4) (b) (4)	26 Aug 2020 19:13:10

US3122090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered 'breaths/min'	System	26 Aug 2020 19:13:10

US3122090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '133'	(b) (4) Aubrey Farray (b) (4) (b) (4)	26 Aug 2020 19:13:10

US3122090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered 'mmHg'	System	26 Aug 2020 19:13:10

US3122090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '85'	(b) (4) Aubrey Farray (b) (4) (b) (4)	26 Aug 2020 19:13:10

US3122090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered 'mmHg'	System	26 Aug 2020 19:13:10

US3122090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User accepted default value 'Post-Dose (POSTDOSE)'	Aubrey Farray (b) (4) (b) (4)	26 Aug 2020 19:13:10

US3122090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Yes (Y)'	(b) (4) Aubrey Farrey (b) (4) (b) (4)	26 Aug 2020 19:13:10

US3122090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '26 Aug 2020'	(b) (4) Aubrey Farray (b) (4)	26 Aug 2020 19:13:10

US3122090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '14:15'	(b) (4) Aubrey Farray (b) (4) (b) (4)	26 Aug 2020 19:13:10

US3122090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered '26 Aug 2020 14:15'	System	26 Aug 2020 19:13:10

US3122090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '98.5' F	(b) (4) Aubrey Farray (b) (4)	26 Aug 2020 19:13:10

US3122090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Oral (Oral)'	(b) (4) Aubrey Farray (b) (4) (b) (4)	26 Aug 2020 19:13:10

US3122090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered empty.	(b) (4) Aubrey Farray (b) (4)	26 Aug 2020 19:13:10

US3122090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '68'	(b) (4) Aubrey Farray (b) (4) (b) (4)	26 Aug 2020 19:13:10

US3122090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered 'bpm'	System	26 Aug 2020 19:13:10

US3122090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '15'	(b) (4) Aubrey Farray (b) (4) (b) (4)	26 Aug 2020 19:13:10

US3122090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered 'breaths/min'	System	26 Aug 2020 19:13:10

US3122090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '135'	(b) (4) Aubrey Farrey (b) (4) (b) (4)	26 Aug 2020 19:13:10

US3122090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered 'mmHg'	System	26 Aug 2020 19:13:10

US3122090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '85'	(b) (4) Aubrey Farray (b) (4) (b) (4)	26 Aug 2020 19:13:10

US3122090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered 'mmHg'	System	26 Aug 2020 19:13:10

US3122090

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:23:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Aubrey Farray (b) (4)	31 Aug 2020 19:37:34
User entered 'Yes (Y)'	(b) (4)	
	Aubrey Farray (b) (4)	26 Aug 2020 19:13:15
	(b) (4)	

US3122090

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:23:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered empty; reason for change Data Entry Error	(b) (4)	
	Aubrey Farray (b) (4)	31 Aug 2020 19:37:34
User entered '26 Aug 2020'	(b) (4)	
	Aubrey Farray (b) (4)	26 Aug 2020 19:13:15
	(b) (4)	

US3122090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 17:35:01

US3122090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 17:35:01

US3122090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

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 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 17:35:01

US3122090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 17:35:01

US3122090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 17:35:01

US3122090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '13:31'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 17:35:01

US3122090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered '26 Aug 2020 13:31'	System	26 Aug 2020 17:35:01

US3122090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 17:35:01

US3122090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered 'ONCE'	System	26 Aug 2020 17:35:01

US3122090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 17:35:01

US3122090

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Yes (Y)'	(b) (4) Aubrey Farrey (b) (4)	26 Aug 2020 19:13:30

US3122090

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '26 Aug 2020'	(b) (4) Aubrey Farrey (b) (4)	26 Aug 2020 19:13:30

US3122090

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '12:39'	(b) (4) Aubrey Farrah (b) (4) (b) (4)	26 Aug 2020 19:13:30

US3122090

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered '26 Aug 2020 12:39'	System	26 Aug 2020 19:13:30

US3122090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:23:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '26 Aug 2020'	(b) (4) Aubrey Farray (b) (4)	26 Aug 2020 19:13:46

US3122090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:23:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Aubrey Farray (b) (4) (b) (4)	26 Aug 2020 19:13:46

US3122090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:23:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Yes (Y)'	(b) (4) Aubrey Farrey (b) (4)	26 Aug 2020 19:13:46

US3122090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:23:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '12:50'	(b) (4) Aubrey Farray (b) (4) (b) (4)	26 Aug 2020 19:13:46

US3122090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered '26 Aug 2020 12:50'	System	26 Aug 2020 19:13:46

US3122090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:23:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Aubrey Farray (b) (4) (b) (4)	26 Aug 2020 19:13:46

US3122090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:23:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'No (N)'	(b) (4) Aubrey Farray (b) (4)	26 Aug 2020 19:13:46

US3122090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:23:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered empty.	(b) (4) Aubrey Farray (b) (4)	26 Aug 2020 19:13:46

US3122090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered empty.	System	26 Aug 2020 19:13:46

US3122090

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Yes (Y)'	(b) (4) Aubrey Farrey (b) (4)	26 Aug 2020 19:13:51

US3122090

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered '1'	System	26 Aug 2020 19:13:51

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	26 Aug 2020 17:35:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-26T13:52:33', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'd54c499f-6f8f-474c-8d53-d2f1f678a95b' User entered 'Yes (Y)'	System	26 Aug 2020 17:53:28
	System	26 Aug 2020 17:53:28

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-26T13:52:42', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'd54c499f-6f8f-474c-8d53-d2f1f678a95b' User entered '98.5'	System	26 Aug 2020 17:53:28
	System	26 Aug 2020 17:53:28

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-26T13:52:47', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'd54c499f-6f8f-474c-8d53-d2f1f678a95b'	System	26 Aug 2020 17:53:28
User entered 'No (N)'	System	26 Aug 2020 17:53:28

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-26T13:52:55', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'd54c499f-6f8f-474c-8d53-d2f1f678a95b' User entered '26 Aug 2020 13:52'	System	26 Aug 2020 17:53:28
	System	26 Aug 2020 17:53:28

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '26 Aug 2020 13:51'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '26 Aug 2020 16:21'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	26 Aug 2020 17:35:01
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-26T17:26:48', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '2e5e9cb2-bf4f-4ea5-b3dd-db2325893a27'	System	26 Aug 2020 21:27:12
User entered 'Yes (Y)'	System	26 Aug 2020 21:27:12

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-26T17:27:01', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '2e5e9cb2-bf4f-4ea5-b3dd-db2325893a27' User entered '97.8'	System	26 Aug 2020 21:27:12
	System	26 Aug 2020 21:27:12

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-26T17:27:05', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '2e5e9cb2-bf4f-4ea5-b3dd-db2325893a27'	System	26 Aug 2020 21:27:12
User entered 'No (N)'	System	26 Aug 2020 21:27:12

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-26T17:27:10', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '2e5e9cb2-bf4f-4ea5-b3dd-db2325893a27'	System	26 Aug 2020 21:27:12
User entered '26 Aug 2020 17:27'	System	26 Aug 2020 21:27:12

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '26 Aug 2020 17:16'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	26 Aug 2020 17:35:01
User entered 'Day 2'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:23:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-27T14:02:47', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'dcabbdcl-ed99-4531-897d-e46f246d8f00' User entered 'Yes (Y)'	System	27 Aug 2020 18:03:20
	System	27 Aug 2020 18:03:20

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:23:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-27T14:02:54', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'dcabbdcl-ed99-4531-897d-e46f246d8f00' User entered '96.5'	System	27 Aug 2020 18:03:20
	System	27 Aug 2020 18:03:20

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-27T14:03:12', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'dcabbdcl-ed99-4531-897d-e46f246d8f00'	System	27 Aug 2020 18:03:20
User entered 'No (N)'	System	27 Aug 2020 18:03:20

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:23:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-27T14:03:16', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'dcabbdcl-ed99-4531-897d-e46f246d8f00'	System	27 Aug 2020 18:03:20
User entered '27 Aug 2020 14:03'	System	27 Aug 2020 18:03:20

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	26 Aug 2020 17:35:01
User entered 'Day 3'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:23:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-28T13:32:50', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'b6360dd7-932e-4370-8533-4b41b9a66dee' User entered 'Yes (Y)'	System	28 Aug 2020 17:33:16
	System	28 Aug 2020 17:33:16

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:23:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-28T13:32:59', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'b6360dd7-932e-4370-8533-4b41b9a66dee' User entered '97.8'	System	28 Aug 2020 17:33:16
	System	28 Aug 2020 17:33:16

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-28T13:33:07', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'b6360dd7-932e-4370-8533-4b41b9a66dee'	System	28 Aug 2020 17:33:16
User entered 'No (N)'	System	28 Aug 2020 17:33:16

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:23:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-28T13:33:11', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'b6360dd7-932e-4370-8533-4b41b9a66dee' User entered '28 Aug 2020 13:33'	System	28 Aug 2020 17:33:16
	System	28 Aug 2020 17:33:16

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	26 Aug 2020 17:35:01
User entered 'Day 4'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:23:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-29T16:56:14', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '71961839-961d-4256-a9c7-f29d813cc58a' User entered 'Yes (Y)'	System	29 Aug 2020 20:56:44
	System	29 Aug 2020 20:56:44

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:23:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-29T16:56:21', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '71961839-961d-4256-a9c7-f29d813cc58a' User entered '98.3'	System	29 Aug 2020 20:56:44
	System	29 Aug 2020 20:56:44

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-29T16:56:31', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '71961839-961d-4256-a9c7-f29d813cc58a' User entered 'No (N)'	System	29 Aug 2020 20:56:44
	System	29 Aug 2020 20:56:44

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:23:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-29T16:56:41', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '71961839-961d-4256-a9c7-f29d813cc58a' User entered '29 Aug 2020 16:56'	System	29 Aug 2020 20:56:44
	System	29 Aug 2020 20:56:44

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	26 Aug 2020 17:35:01
User entered 'Day 5'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:23:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-30T16:17:04', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '9b834b8f-bedb-43bd-a160-620752b0fa71' User entered 'Yes (Y)'	System	30 Aug 2020 20:17:38
	System	30 Aug 2020 20:17:38

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:23:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-30T16:17:20', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '9b834b8f-bedb-43bd-a160-620752b0fa71' User entered '98.5'	System	30 Aug 2020 20:17:38
	System	30 Aug 2020 20:17:38

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-30T16:17:26', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '9b834b8f-bedb-43bd-a160-620752b0fa71' User entered 'No (N)'	System	30 Aug 2020 20:17:38
	System	30 Aug 2020 20:17:38

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:23:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-30T16:17:37', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '9b834b8f-bedb-43bd-a160-620752b0fa71' User entered '30 Aug 2020 16:17'	System	30 Aug 2020 20:17:38
	System	30 Aug 2020 20:17:38

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	26 Aug 2020 17:35:01
User entered 'Day 6'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:23:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-31T15:29:15', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '397bb5cb-e4a9-47a7-8746-560500acf8e1' User entered 'Yes (Y)'	System	31 Aug 2020 19:31:57
	System	31 Aug 2020 19:31:57

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:23:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-31T15:29:30', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '397bb5cb-e4a9-47a7-8746-560500acf8e1' User entered '98.2'	System	31 Aug 2020 19:31:57
	System	31 Aug 2020 19:31:57

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-31T15:29:34', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '397bb5cb-e4a9-47a7-8746-560500acf8e1' User entered 'No (N)'	System	31 Aug 2020 19:31:57
	System	31 Aug 2020 19:31:57

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:23:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-31T15:29:38', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '397bb5cb-e4a9-47a7-8746-560500acf8e1' User entered '31 Aug 2020 15:29'	System	31 Aug 2020 19:31:57
	System	31 Aug 2020 19:31:57

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	26 Aug 2020 17:35:01
User entered 'Day 7'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:23:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-09-02T01:21:52', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'a8e5df1c-3244-47e6-8e1c-f6d1dc5d8862' User entered 'Yes (Y)'	System	02 Sep 2020 05:22:52
	System	02 Sep 2020 05:22:52

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:23:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-09-02T01:22:37', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'a8e5df1c-3244-47e6-8e1c-f6d1dc5d8862' User entered '98.2'	System	02 Sep 2020 05:22:52
	System	02 Sep 2020 05:22:52

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-09-02T01:22:44', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'a8e5df1c-3244-47e6-8e1c-f6d1dc5d8862'	System	02 Sep 2020 05:22:52
User entered 'No (N)'	System	02 Sep 2020 05:22:52

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:23:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-09-02T01:22:50', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'a8e5df1c-3244-47e6-8e1c-f6d1dc5d8862'	System	02 Sep 2020 05:22:52
User entered '02 Sep 2020 01:22'	System	02 Sep 2020 05:22:52

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	26 Aug 2020 17:35:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-26T13:53:04', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '79c1c1e7-b290-4285-a3ad-f348621db04a' User entered 'None (1)'	System	26 Aug 2020 17:53:34
	System	26 Aug 2020 17:53:34

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-26T13:53:15', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '79c1c1e7-b290-4285-a3ad-f348621db04a' User entered 'No (N)'	System	26 Aug 2020 17:53:34
	System	26 Aug 2020 17:53:34

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-26T13:53:19', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '79c1c1e7-b290-4285-a3ad-f348621db04a' User entered 'No (N)'	System	26 Aug 2020 17:53:34
	System	26 Aug 2020 17:53:34

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-26T13:53:23', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '79c1c1e7-b290-4285-a3ad-f348621db04a' User entered 'None (1)'	System	26 Aug 2020 17:53:34
	System	26 Aug 2020 17:53:34

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-26T13:53:29', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '79c1c1e7-b290-4285-a3ad-f348621db04a' User entered '26 Aug 2020 13:53'	System	26 Aug 2020 17:53:34
	System	26 Aug 2020 17:53:34

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '26 Aug 2020 13:51'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '26 Aug 2020 16:21'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	26 Aug 2020 17:35:01
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-26T17:27:16', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'b92f539c-f1f3-4947-b3ac-39de6401f200' User entered 'None (1)'	System	26 Aug 2020 21:27:37
	System	26 Aug 2020 21:27:37

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-26T17:27:21', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'b92f539c-f1f3-4947-b3ac-39de6401f200'	System	26 Aug 2020 21:27:37
User entered 'No (N)'	System	26 Aug 2020 21:27:37

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-26T17:27:28', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'b92f539c-f1f3-4947-b3ac-39de6401f200'	System	26 Aug 2020 21:27:37
User entered 'No (N)'	System	26 Aug 2020 21:27:37

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-26T17:27:31', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'b92f539c-f1f3-4947-b3ac-39de6401f200'	System	26 Aug 2020 21:27:37
User entered 'None (1)'	System	26 Aug 2020 21:27:37

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-26T17:27:36', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'b92f539c-f1f3-4947-b3ac-39de6401f200' User entered '26 Aug 2020 17:27'	System	26 Aug 2020 21:27:37
	System	26 Aug 2020 21:27:37

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '26 Aug 2020 17:16'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	26 Aug 2020 17:35:01
User entered 'Day 2'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-27T14:03:21', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '14ef3e6a-22bf-4443-b0cc-4698c96aa23b'	System	27 Aug 2020 18:03:45
User entered 'None (1)'	System	27 Aug 2020 18:03:45

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-27T14:03:32', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '14ef3e6a-22bf-4443-b0cc-4698c96aa23b' User entered 'No (N)'	System	27 Aug 2020 18:03:45
	System	27 Aug 2020 18:03:45

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-27T14:03:35', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '14ef3e6a-22bf-4443-b0cc-4698c96aa23b'	System	27 Aug 2020 18:03:45
User entered 'No (N)'	System	27 Aug 2020 18:03:45

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-27T14:03:38', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '14ef3e6a-22bf-4443-b0cc-4698c96aa23b'	System	27 Aug 2020 18:03:45
User entered 'None (1)'	System	27 Aug 2020 18:03:45

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-27T14:03:42', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '14ef3e6a-22bf-4443-b0cc-4698c96aa23b' User entered '27 Aug 2020 14:03'	System	27 Aug 2020 18:03:45
	System	27 Aug 2020 18:03:45

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	26 Aug 2020 17:35:01
User entered 'Day 3'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-28T13:33:15', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '946b8850-e686-40ca-a4ea-7125c79d1798' User entered 'None (1)'	System	28 Aug 2020 17:33:37
	System	28 Aug 2020 17:33:37

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-28T13:33:19', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '946b8850-e686-40ca-a4ea-7125c79d1798' User entered 'No (N)'	System	28 Aug 2020 17:33:37
	System	28 Aug 2020 17:33:37

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-28T13:33:22', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '946b8850-e686-40ca-a4ea-7125c79d1798'	System	28 Aug 2020 17:33:37
User entered 'No (N)'	System	28 Aug 2020 17:33:37

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-28T13:33:29', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '946b8850-e686-40ca-a4ea-7125c79d1798'	System	28 Aug 2020 17:33:37
User entered 'None (1)'	System	28 Aug 2020 17:33:37

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-28T13:33:32', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '946b8850-e686-40ca-a4ea-7125c79d1798' User entered '28 Aug 2020 13:33'	System	28 Aug 2020 17:33:37
	System	28 Aug 2020 17:33:37

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	26 Aug 2020 17:35:01
User entered 'Day 4'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-29T16:56:46', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '65258b57-c5f9-4a32-ae07-00d7e8da1909' User entered 'None (1)'	System	29 Aug 2020 20:57:05
	System	29 Aug 2020 20:57:05

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-29T16:56:49', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '65258b57-c5f9-4a32-ae07-00d7e8da1909' User entered 'No (N)'	System	29 Aug 2020 20:57:05
	System	29 Aug 2020 20:57:05

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-29T16:56:52', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '65258b57-c5f9-4a32-ae07-00d7e8da1909' User entered 'No (N)'	System	29 Aug 2020 20:57:05
	System	29 Aug 2020 20:57:05

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-29T16:56:55', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '65258b57-c5f9-4a32-ae07-00d7e8da1909' User entered 'None (1)'	System	29 Aug 2020 20:57:05
	System	29 Aug 2020 20:57:05

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-29T16:57:02', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '65258b57-c5f9-4a32-ae07-00d7e8da1909' User entered '29 Aug 2020 16:57'	System	29 Aug 2020 20:57:05
	System	29 Aug 2020 20:57:05

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	26 Aug 2020 17:35:01
User entered 'Day 5'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-30T16:17:51', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '47b346ce-aa3d-441f-aede-dabbeabfb55e' User entered 'None (1)'	System	30 Aug 2020 20:18:19
	System	30 Aug 2020 20:18:19

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-30T16:18:04', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '47b346ce-aa3d-441f-aede-dabbeabfb55e' User entered 'No (N)'	System	30 Aug 2020 20:18:19
	System	30 Aug 2020 20:18:19

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-30T16:18:07', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '47b346ce-aa3d-441f-aede-dabbeabfb55e' User entered 'No (N)'	System	30 Aug 2020 20:18:19
	System	30 Aug 2020 20:18:19

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-30T16:18:11', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '47b346ce-aa3d-441f-aede-dabbeabfb55e' User entered 'None (1)'	System	30 Aug 2020 20:18:19
	System	30 Aug 2020 20:18:19

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-30T16:18:16', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '47b346ce-aa3d-441f-aede-dabbeabfb55e' User entered '30 Aug 2020 16:18'	System	30 Aug 2020 20:18:19
	System	30 Aug 2020 20:18:19

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	26 Aug 2020 17:35:01
User entered 'Day 6'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-31T15:29:42', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '3f29612f-4014-4a73-8cb1-8a4675eec5e0' User entered 'None (1)'	System	31 Aug 2020 19:32:05
	System	31 Aug 2020 19:32:05

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-31T15:29:46', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '3f29612f-4014-4a73-8cb1-8a4675eec5e0' User entered 'No (N)'	System	31 Aug 2020 19:32:05
	System	31 Aug 2020 19:32:05

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-31T15:29:49', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '3f29612f-4014-4a73-8cb1-8a4675eec5e0' User entered 'No (N)'	System	31 Aug 2020 19:32:05
	System	31 Aug 2020 19:32:05

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-31T15:29:52', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '3f29612f-4014-4a73-8cb1-8a4675eec5e0' User entered 'None (1)'	System	31 Aug 2020 19:32:05
	System	31 Aug 2020 19:32:05

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-31T15:29:55', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '3f29612f-4014-4a73-8cb1-8a4675eec5e0' User entered '31 Aug 2020 15:29'	System	31 Aug 2020 19:32:05
	System	31 Aug 2020 19:32:05

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	26 Aug 2020 17:35:01
User entered 'Day 7'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-09-02T01:22:57', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '061ee13d-3664-4b87-89d1-156417eaa8f2'	System	02 Sep 2020 05:23:17
User entered 'None (1)'	System	02 Sep 2020 05:23:17

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-09-02T01:23:01', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '061ee13d-3664-4b87-89d1-156417eaa8f2' User entered 'No (N)'	System	02 Sep 2020 05:23:17
	System	02 Sep 2020 05:23:17

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-09-02T01:23:05', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '061ee13d-3664-4b87-89d1-156417eaa8f2' User entered 'No (N)'	System	02 Sep 2020 05:23:17
	System	02 Sep 2020 05:23:17

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-09-02T01:23:11', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '061ee13d-3664-4b87-89d1-156417eaa8f2'	System	02 Sep 2020 05:23:17
User entered 'None (1)'	System	02 Sep 2020 05:23:17

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-09-02T01:23:14', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '061ee13d-3664-4b87-89d1-156417eaa8f2' User entered '02 Sep 2020 01:23'	System	02 Sep 2020 05:23:17
	System	02 Sep 2020 05:23:17

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	26 Aug 2020 17:35:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-26T13:53:38', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '3f3085e6-a625-4ad6-95f1-a60f633e89a6' User entered 'None (0)'	System	26 Aug 2020 17:54:14
	System	26 Aug 2020 17:54:14

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-26T13:53:42', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '3f3085e6-a625-4ad6-95f1-a60f633e89a6' User entered 'None (0)'	System	26 Aug 2020 17:54:14
	System	26 Aug 2020 17:54:14

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-26T13:53:45', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '3f3085e6-a625-4ad6-95f1-a60f633e89a6' User entered 'None (0)'	System	26 Aug 2020 17:54:14
	System	26 Aug 2020 17:54:14

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-26T13:53:48', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '3f3085e6-a625-4ad6-95f1-a60f633e89a6' User entered 'None (0)'	System	26 Aug 2020 17:54:14
	System	26 Aug 2020 17:54:14

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-26T13:53:51', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '3f3085e6-a625-4ad6-95f1-a60f633e89a6' User entered 'None (0)'	System	26 Aug 2020 17:54:14
	System	26 Aug 2020 17:54:14

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-26T13:53:54', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '3f3085e6-a625-4ad6-95f1-a60f633e89a6' User entered 'None (0)'	System	26 Aug 2020 17:54:14
	System	26 Aug 2020 17:54:14

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-26T13:54:07', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '3f3085e6-a625-4ad6-95f1-a60f633e89a6' User entered 'No (N)'	System	26 Aug 2020 17:54:14
	System	26 Aug 2020 17:54:14

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-26T13:54:11', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '3f3085e6-a625-4ad6-95f1-a60f633e89a6' User entered '26 Aug 2020 13:54'	System	26 Aug 2020 17:54:14
	System	26 Aug 2020 17:54:14

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '26 Aug 2020 13:51'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '26 Aug 2020 16:21'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	26 Aug 2020 17:35:01
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-26T17:27:42', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '0f8562d7-32a0-4836-8353-74223f6c681b' User entered 'None (0)'	System	26 Aug 2020 21:28:04
	System	26 Aug 2020 21:28:04

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-26T17:27:44', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '0f8562d7-32a0-4836-8353-74223f6c681b' User entered 'None (0)'	System	26 Aug 2020 21:28:04
	System	26 Aug 2020 21:28:04

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-26T17:27:47', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '0f8562d7-32a0-4836-8353-74223f6c681b' User entered 'None (0)'	System	26 Aug 2020 21:28:04
	System	26 Aug 2020 21:28:04

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-26T17:27:49', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '0f8562d7-32a0-4836-8353-74223f6c681b' User entered 'None (0)'	System	26 Aug 2020 21:28:04
	System	26 Aug 2020 21:28:04

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-26T17:27:51', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '0f8562d7-32a0-4836-8353-74223f6c681b' User entered 'None (0)'	System	26 Aug 2020 21:28:04
	System	26 Aug 2020 21:28:04

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-26T17:27:53', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '0f8562d7-32a0-4836-8353-74223f6c681b' User entered 'None (0)'	System	26 Aug 2020 21:28:04
	System	26 Aug 2020 21:28:04

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-26T17:27:56', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '0f8562d7-32a0-4836-8353-74223f6c681b' User entered 'No (N)'	System	26 Aug 2020 21:28:04
	System	26 Aug 2020 21:28:04

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-26T17:27:59', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '0f8562d7-32a0-4836-8353-74223f6c681b' User entered '26 Aug 2020 17:27'	System	26 Aug 2020 21:28:04
	System	26 Aug 2020 21:28:04

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '26 Aug 2020 17:16'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	26 Aug 2020 17:35:01
User entered 'Day 2'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-27T14:03:55', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '9e3a8ed2-7e09-4999-bfc1-03afc01a12b1'	System	27 Aug 2020 18:04:24
User entered 'No interference with activity (1)'	System	27 Aug 2020 18:04:24

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-27T14:04:03', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '9e3a8ed2-7e09-4999-bfc1-03afc01a12b1' User entered 'None (0)'	System	27 Aug 2020 18:04:24
	System	27 Aug 2020 18:04:24

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-27T14:04:06', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '9e3a8ed2-7e09-4999-bfc1-03afc01a12b1' User entered 'None (0)'	System	27 Aug 2020 18:04:24
	System	27 Aug 2020 18:04:24

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-27T14:04:08', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '9e3a8ed2-7e09-4999-bfc1-03afc01a12b1' User entered 'None (0)'	System	27 Aug 2020 18:04:24
	System	27 Aug 2020 18:04:24

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-27T14:04:11', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '9e3a8ed2-7e09-4999-bfc1-03afc01a12b1' User entered 'None (0)'	System	27 Aug 2020 18:04:24
	System	27 Aug 2020 18:04:24

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-27T14:04:13', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '9e3a8ed2-7e09-4999-bfc1-03afc01a12b1' User entered 'None (0)'	System	27 Aug 2020 18:04:24
	System	27 Aug 2020 18:04:24

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-27T14:04:17', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '9e3a8ed2-7e09-4999-bfc1-03afc01a12b1' User entered 'No (N)'	System	27 Aug 2020 18:04:24
	System	27 Aug 2020 18:04:24

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-27T14:04:22', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '9e3a8ed2-7e09-4999-bfc1-03afc01a12b1' User entered '27 Aug 2020 14:04'	System	27 Aug 2020 18:04:24
	System	27 Aug 2020 18:04:24

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	26 Aug 2020 17:35:01
User entered 'Day 3'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-28T13:33:43', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7a63f38f-9a0d-4332-9666-7e2b7b338ae5' User entered 'None (0)'	System	28 Aug 2020 17:34:13
	System	28 Aug 2020 17:34:13

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-28T13:33:48', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7a63f38f-9a0d-4332-9666-7e2b7b338ae5' User entered 'None (0)'	System	28 Aug 2020 17:34:13
	System	28 Aug 2020 17:34:13

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-28T13:33:53', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7a63f38f-9a0d-4332-9666-7e2b7b338ae5' User entered 'None (0)'	System	28 Aug 2020 17:34:13
	System	28 Aug 2020 17:34:13

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-28T13:33:56', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7a63f38f-9a0d-4332-9666-7e2b7b338ae5' User entered 'None (0)'	System	28 Aug 2020 17:34:13
	System	28 Aug 2020 17:34:13

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-28T13:33:58', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7a63f38f-9a0d-4332-9666-7e2b7b338ae5' User entered 'None (0)'	System	28 Aug 2020 17:34:13
	System	28 Aug 2020 17:34:13

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-28T13:34:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7a63f38f-9a0d-4332-9666-7e2b7b338ae5' User entered 'None (0)'	System	28 Aug 2020 17:34:13
	System	28 Aug 2020 17:34:13

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-28T13:34:04', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7a63f38f-9a0d-4332-9666-7e2b7b338ae5' User entered 'No (N)'	System	28 Aug 2020 17:34:13
	System	28 Aug 2020 17:34:13

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-28T13:34:10', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7a63f38f-9a0d-4332-9666-7e2b7b338ae5' User entered '28 Aug 2020 13:34'	System	28 Aug 2020 17:34:13
	System	28 Aug 2020 17:34:13

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	26 Aug 2020 17:35:01
User entered 'Day 4'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-29T16:57:15', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'd40fa5c8-0c75-42a8-a2c1-c2307077d283'	System	29 Aug 2020 20:57:51
User entered 'No interference with activity (1)'	System	29 Aug 2020 20:57:51

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-29T16:57:28', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'd40fa5c8-0c75-42a8-a2c1-c2307077d283' User entered 'None (0)'	System	29 Aug 2020 20:57:51
	System	29 Aug 2020 20:57:51

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-29T16:57:31', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'd40fa5c8-0c75-42a8-a2c1-c2307077d283' User entered 'None (0)'	System	29 Aug 2020 20:57:51
	System	29 Aug 2020 20:57:51

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-29T16:57:34', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'd40fa5c8-0c75-42a8-a2c1-c2307077d283' User entered 'None (0)'	System	29 Aug 2020 20:57:51
	System	29 Aug 2020 20:57:51

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-29T16:57:36', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'd40fa5c8-0c75-42a8-a2c1-c2307077d283' User entered 'None (0)'	System	29 Aug 2020 20:57:51
	System	29 Aug 2020 20:57:51

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-29T16:57:40', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'd40fa5c8-0c75-42a8-a2c1-c2307077d283' User entered 'None (0)'	System	29 Aug 2020 20:57:51
	System	29 Aug 2020 20:57:51

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-29T16:57:44', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'd40fa5c8-0c75-42a8-a2c1-c2307077d283'	System	29 Aug 2020 20:57:51
User entered 'No (N)'	System	29 Aug 2020 20:57:51

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-29T16:57:49', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'd40fa5c8-0c75-42a8-a2c1-c2307077d283' User entered '29 Aug 2020 16:57'	System	29 Aug 2020 20:57:51
	System	29 Aug 2020 20:57:51

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	26 Aug 2020 17:35:01
User entered 'Day 5'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-30T16:18:34', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7e9ddcdc-c1fd-4546-9898-6e11e0a78533'	System	30 Aug 2020 20:19:25
User entered 'No interference with activity (1)'	System	30 Aug 2020 20:19:25

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-30T16:18:38', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7e9ddcdc-c1fd-4546-9898-6e11e0a78533' User entered 'None (0)'	System	30 Aug 2020 20:19:25
	System	30 Aug 2020 20:19:25

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-30T16:18:41', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7e9ddcdc-c1fd-4546-9898-6e11e0a78533' User entered 'None (0)'	System	30 Aug 2020 20:19:25
	System	30 Aug 2020 20:19:25

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-30T16:18:49', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7e9ddcdc-c1fd-4546-9898-6e11e0a78533' User entered 'None (0)'	System	30 Aug 2020 20:19:25
	System	30 Aug 2020 20:19:25

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-30T16:18:51', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7e9ddcdc-c1fd-4546-9898-6e11e0a78533' User entered 'None (0)'	System	30 Aug 2020 20:19:25
	System	30 Aug 2020 20:19:25

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-30T16:18:55', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7e9ddcdc-c1fd-4546-9898-6e11e0a78533' User entered 'None (0)'	System	30 Aug 2020 20:19:25
	System	30 Aug 2020 20:19:25

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-30T16:19:19', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7e9ddcdc-c1fd-4546-9898-6e11e0a78533'	System	30 Aug 2020 20:19:25
User entered 'No (N)'	System	30 Aug 2020 20:19:25

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-30T16:19:24', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7e9ddcdc-c1fd-4546-9898-6e11e0a78533' User entered '30 Aug 2020 16:19'	System	30 Aug 2020 20:19:25
	System	30 Aug 2020 20:19:25

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	26 Aug 2020 17:35:01
User entered 'Day 6'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-31T15:30:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '62b2e8d3-d11a-4616-afb8-530600335bc3' User entered 'None (0)'	System	31 Aug 2020 19:32:17
	System	31 Aug 2020 19:32:17

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-31T15:30:03', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '62b2e8d3-d11a-4616-afb8-530600335bc3' User entered 'None (0)'	System	31 Aug 2020 19:32:17
	System	31 Aug 2020 19:32:17

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-31T15:30:06', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '62b2e8d3-d11a-4616-afb8-530600335bc3' User entered 'None (0)'	System	31 Aug 2020 19:32:17
	System	31 Aug 2020 19:32:17

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-31T15:30:09', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '62b2e8d3-d11a-4616-afb8-530600335bc3' User entered 'None (0)'	System	31 Aug 2020 19:32:17
	System	31 Aug 2020 19:32:17

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-31T15:30:11', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '62b2e8d3-d11a-4616-afb8-530600335bc3' User entered 'None (0)'	System	31 Aug 2020 19:32:17
	System	31 Aug 2020 19:32:17

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-31T15:30:14', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '62b2e8d3-d11a-4616-afb8-530600335bc3' User entered 'None (0)'	System	31 Aug 2020 19:32:17
	System	31 Aug 2020 19:32:17

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-31T15:30:17', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '62b2e8d3-d11a-4616-afb8-530600335bc3' User entered 'No (N)'	System	31 Aug 2020 19:32:17
	System	31 Aug 2020 19:32:17

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-08-31T15:30:20', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '62b2e8d3-d11a-4616-afb8-530600335bc3' User entered '31 Aug 2020 15:30'	System	31 Aug 2020 19:32:17
	System	31 Aug 2020 19:32:17

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	26 Aug 2020 17:35:01
User entered 'Day 7'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-09-02T01:23:20', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '39df39b6-3d22-43aa-bb3b-204a368ecfc0' User entered 'None (0)'	System	02 Sep 2020 05:24:06
	System	02 Sep 2020 05:24:06

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-09-02T01:23:25', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '39df39b6-3d22-43aa-bb3b-204a368ecfc0' User entered 'None (0)'	System	02 Sep 2020 05:24:06
	System	02 Sep 2020 05:24:06

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-09-02T01:23:33', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '39df39b6-3d22-43aa-bb3b-204a368ecfc0' User entered 'None (0)'	System	02 Sep 2020 05:24:06
	System	02 Sep 2020 05:24:06

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-09-02T01:23:38', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '39df39b6-3d22-43aa-bb3b-204a368ecfc0' User entered 'None (0)'	System	02 Sep 2020 05:24:06
	System	02 Sep 2020 05:24:06

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-09-02T01:23:42', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '39df39b6-3d22-43aa-bb3b-204a368ecfc0' User entered 'None (0)'	System	02 Sep 2020 05:24:06
	System	02 Sep 2020 05:24:06

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-09-02T01:23:51', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '39df39b6-3d22-43aa-bb3b-204a368ecfc0' User entered 'None (0)'	System	02 Sep 2020 05:24:06
	System	02 Sep 2020 05:24:06

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-09-02T01:23:55', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '39df39b6-3d22-43aa-bb3b-204a368ecfc0' User entered 'No (N)'	System	02 Sep 2020 05:24:06
	System	02 Sep 2020 05:24:06

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-09-02T01:24:03', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '39df39b6-3d22-43aa-bb3b-204a368ecfc0' User entered '02 Sep 2020 01:24'	System	02 Sep 2020 05:24:06
	System	02 Sep 2020 05:24:06

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 17:35:01

US3122090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:23:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 17:35:01

US3122090

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	04 Sep 2020 14:14:13

US3122090

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '03 Sep 2020'	(b) (4) Leah Corts (b) (4)	04 Sep 2020 14:14:13

US3122090

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Leah Corts (b) (4)	04 Sep 2020 14:14:13

US3122090

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered empty.	(b) (4) Leah Corts (b) (4)	04 Sep 2020 14:14:13

US3122090

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	04 Sep 2020 14:14:18

US3122090

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User entered 'I'	System	04 Sep 2020 14:14:18

US3122090

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 19:28:03

US3122090

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 19:28:03

US3122090

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 19:28:03

US3122090

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 19:28:03

US3122090

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 19:27:54

US3122090

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User entered 'I'	System	11 Sep 2020 19:27:54

US3122090

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:17:38

US3122090

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:17:38

US3122090

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:17:38

US3122090

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:17:38

US3122090

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:17:28

US3122090

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:51:10
User entered 'I'	System	18 Sep 2020 19:17:28

US3122090

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	30 Sep 2020 14:53:47

US3122090

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '30 Sep 2020'	(b) (4) Leah Corts (b) (4)	30 Sep 2020 14:53:47

US3122090

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:12

[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 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Clinic (Clinic)'	Leah Corts (b) (4)	30 Sep 2020 14:53:47

US3122090

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered 'VISIT3'	System	30 Sep 2020 14:53:47

US3122090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	30 Sep 2020 14:53:53

US3122090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered empty.	(b) (4) Leah Corts (b) (4)	30 Sep 2020 14:53:53

US3122090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered empty.	(b) (4) Leah Corts (b) (4)	30 Sep 2020 14:53:53

US3122090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered empty.	System	30 Sep 2020 14:53:53

US3122090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered empty.	(b) (4) Leah Corts (b) (4)	30 Sep 2020 14:53:53

US3122090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered empty.	(b) (4)	30 Sep 2020 14:53:53
	Leah Corts (b) (4)	

US3122090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered empty.	(b) (4) Leah Corts (b) (4)	30 Sep 2020 14:53:53

US3122090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered empty.	(b) (4) Leah Corts (b) (4)	30 Sep 2020 14:53:53

US3122090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered empty.	System	30 Sep 2020 14:53:53

US3122090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered empty.	(b) (4) Leah Corts (b) (4)	30 Sep 2020 14:53:53

US3122090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered empty.	System	30 Sep 2020 14:53:53

US3122090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered empty.	(b) (4) Leah Corts (b) (4)	30 Sep 2020 14:53:53

US3122090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered empty.	System	30 Sep 2020 14:53:53

US3122090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered empty.	(b) (4) Leah Corts (b) (4)	30 Sep 2020 14:53:53

US3122090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered empty.	System	30 Sep 2020 14:53:53

US3122090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01

US3122090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01

US3122090

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:23:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	30 Sep 2020 14:53:58

US3122090

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:23:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered empty.	(b) (4) Leah Corts (b) (4)	30 Sep 2020 14:53:58

US3122090

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	30 Sep 2020 14:54:12

US3122090

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '30 Sep 2020'	(b) (4) Leah Corts (b) (4)	30 Sep 2020 14:54:12

US3122090

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '09:25'	(b) (4) Leah Corts (b) (4)	30 Sep 2020 14:54:12

US3122090

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered '30 Sep 2020 09:25'	System	30 Sep 2020 14:54:12

US3122090

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	30 Sep 2020 14:54:18

US3122090

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered 'I'	System	30 Sep 2020 14:54:18

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered 'Day 64'	System	29 Jul 2020 14:47:17

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-09-28T14:43:09', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '4b3bea0d-516f-4c94-9c34-699fc06ab939'	System	29 Sep 2020 02:18:38
User entered 'No (N)'	System	29 Sep 2020 02:18:38

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

Have you been exposed to someone with 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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-09-28T14:43:49', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '4b3bea0d-516f-4c94-9c34-699fc06ab939'	System	29 Sep 2020 02:18:38
User entered 'No (N)'	System	29 Sep 2020 02:18:38

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-09-28T14:43:54', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '4b3bea0d-516f-4c94-9c34-699fc06ab939' User entered '28 Sep 2020 14:43:54'	System	29 Sep 2020 02:18:38
	System	29 Sep 2020 02:18:38

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered '28 Sep 2020 00:01'	System	29 Jul 2020 14:47:17

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered '02 Oct 2020 23:59'	System	29 Jul 2020 14:47:17

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered 'Day 71'	System	29 Jul 2020 14:47:17

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-10-05T04:08:49', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '40df32bf-f4c9-492c-8568-d43d84b5646f' User entered 'No (N)'	System	05 Oct 2020 08:09:08
	System	05 Oct 2020 08:09:08

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

Have you been exposed to someone with 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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-10-05T04:08:57', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '40df32bf-f4c9-492c-8568-d43d84b5646f' User entered 'No (N)'	System	05 Oct 2020 08:09:08
	System	05 Oct 2020 08:09:08

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-10-05T04:09:06', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '40df32bf-f4c9-492c-8568-d43d84b5646f' User entered '05 Oct 2020 04:09:06'	System	05 Oct 2020 08:09:08
	System	05 Oct 2020 08:09:08

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered '05 Oct 2020 00:01'	System	29 Jul 2020 14:47:17

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered '09 Oct 2020 23:59'	System	29 Jul 2020 14:47:17

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered 'Day 78'	System	29 Jul 2020 14:47:17

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-10-12T00:31:50', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '907cd246-2747-49e2-a672-51f779acab18' User entered 'No (N)'	System	12 Oct 2020 04:32:21
	System	12 Oct 2020 04:32:21

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

Have you been exposed to someone with 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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-10-12T00:32:07', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '907cd246-2747-49e2-a672-51f779acab18' User entered 'No (N)'	System	12 Oct 2020 04:32:21
	System	12 Oct 2020 04:32:21

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-10-12T00:32:19', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '907cd246-2747-49e2-a672-51f779acab18' User entered '12 Oct 2020 00:32:19'	System	12 Oct 2020 04:32:21
	System	12 Oct 2020 04:32:21

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered '12 Oct 2020 00:01'	System	29 Jul 2020 14:47:17

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered '16 Oct 2020 23:59'	System	29 Jul 2020 14:47:17

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered 'Day 92'	System	29 Jul 2020 14:47:17

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-10-26T03:31:24', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '5cdd0259-e77f-42f9-b37f-07aec175a8fb' User entered 'No (N)'	System	26 Oct 2020 07:32:23
	System	26 Oct 2020 07:32:23

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

Have you been exposed to someone with 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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-10-26T03:31:52', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '5cdd0259-e77f-42f9-b37f-07aec175a8fb' User entered 'No (N)'	System	26 Oct 2020 07:32:23
	System	26 Oct 2020 07:32:23

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-10-26T03:32:20', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '5cdd0259-e77f-42f9-b37f-07aec175a8fb' User entered '26 Oct 2020 03:32:20'	System	26 Oct 2020 07:32:23
	System	26 Oct 2020 07:32:23

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered '26 Oct 2020 00:01'	System	29 Jul 2020 14:47:17

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered '30 Oct 2020 23:59'	System	29 Jul 2020 14:47:17

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered 'Day 99'	System	29 Jul 2020 14:47:17

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-11-02T18:49:52', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'c0f9de0f-0e3d-4c7d-9c73-cd4cea975e17'	System	02 Nov 2020 23:50:37
User entered 'No (N)'	System	02 Nov 2020 23:50:37

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

Have you been exposed to someone with 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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-11-02T18:50:18', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'c0f9de0f-0e3d-4c7d-9c73-cd4cea975e17'	System	02 Nov 2020 23:50:37
User entered 'No (N)'	System	02 Nov 2020 23:50:37

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-11-02T18:50:31', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'c0f9de0f-0e3d-4c7d-9c73-cd4cea975e17' User entered '02 Nov 2020 18:50:31'	System	02 Nov 2020 23:50:37
	System	02 Nov 2020 23:50:37

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered '02 Nov 2020 00:01'	System	29 Jul 2020 14:47:17

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered '06 Nov 2020 23:59'	System	29 Jul 2020 14:47:17

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered 'Day 106'	System	29 Jul 2020 14:47:17

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-11-09T03:30:29', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'fddaf1a0-ae99-4c56-acea-6366c2b302d3'	System	09 Nov 2020 08:30:46
User entered 'No (N)'	System	09 Nov 2020 08:30:46

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

Have you been exposed to someone with 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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-11-09T03:30:35', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'fddaf1a0-ae99-4c56-acea-6366c2b302d3'	System	09 Nov 2020 08:30:46
User entered 'No (N)'	System	09 Nov 2020 08:30:46

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-11-09T03:30:43', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'fddaf1a0-ae99-4c56-acea-6366c2b302d3' User entered '09 Nov 2020 03:30:43'	System	09 Nov 2020 08:30:46
	System	09 Nov 2020 08:30:46

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered '09 Nov 2020 00:01'	System	29 Jul 2020 14:47:17

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered '13 Nov 2020 23:59'	System	29 Jul 2020 14:47:17

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered 'Day 113'	System	29 Jul 2020 14:47:17

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-11-16T00:15:12', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '97c92c23-571a-47cc-a07f-31d578a189b0' User entered 'No (N)'	System	16 Nov 2020 06:15:34
	System	16 Nov 2020 06:15:34

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

Have you been exposed to someone with 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 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-11-16T00:15:18', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '97c92c23-571a-47cc-a07f-31d578a189b0' User entered 'No (N)'	System	16 Nov 2020 06:15:34
	System	16 Nov 2020 06:15:34

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-11-16T00:15:30', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '97c92c23-571a-47cc-a07f-31d578a189b0' User entered '16 Nov 2020 00:15:30'	System	16 Nov 2020 06:15:34
	System	16 Nov 2020 06:15:34

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered '16 Nov 2020 00:01'	System	29 Jul 2020 14:47:17

US3122090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:37
Data entry locked.	System	29 Jul 2020 14:47:17
User entered '20 Nov 2020 23:59'	System	29 Jul 2020 14:47:17

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-11-27T18:42:02', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'a273fb7d-27f0-47df-aed6-dba3c025d991'	System	27 Nov 2020 23:42:25
User entered 'No (N)'	System	27 Nov 2020 23:42:25

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Have you been exposed to someone with 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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-11-27T18:42:12', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'a273fb7d-27f0-47df-aed6-dba3c025d991'	System	27 Nov 2020 23:42:25
User entered 'No (N)'	System	27 Nov 2020 23:42:25

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-11-27T18:42:23', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'a273fb7d-27f0-47df-aed6-dba3c025d991' User entered '27 Nov 2020 18:42:23'	System	27 Nov 2020 23:42:25
	System	27 Nov 2020 23:42:25

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-12-04T08:56:45', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '170bccb2-b47b-4742-b371-d881551fcbba' User entered 'Yes (Y)'	System	04 Dec 2020 13:57:48
	System	04 Dec 2020 13:57:48

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Have you been exposed to someone with 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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-12-04T08:56:49', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '170bccb2-b47b-4742-b371-d881551fcbba' User entered 'No (N)'	System	04 Dec 2020 13:57:48
	System	04 Dec 2020 13:57:48

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-12-04T08:57:02', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '170bccb2-b47b-4742-b371-d881551fcbba' User entered 'No (N)'	System	04 Dec 2020 13:57:48
	System	04 Dec 2020 13:57:48

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-12-04T08:57:11', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '170bccb2-b47b-4742-b371-d881551fcbba' User entered 'No (N)'	System	04 Dec 2020 13:57:48
	System	04 Dec 2020 13:57:48

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-12-04T08:57:44', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '170bccb2-b47b-4742-b371-d881551fcbba' User entered '04 Dec 2020 08:57:44'	System	04 Dec 2020 13:57:48
	System	04 Dec 2020 13:57:48

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-12-12T16:17:54', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '024f4180-490c-460b-99b5-88bbbbe86b54'	System	12 Dec 2020 21:18:09
User entered 'No (N)'	System	12 Dec 2020 21:18:09

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Have you been exposed to someone with 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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-12-12T16:17:59', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '024f4180-490c-460b-99b5-88bbbbe86b54'	System	12 Dec 2020 21:18:09
User entered 'No (N)'	System	12 Dec 2020 21:18:09

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-12-12T16:18:06', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '024f4180-490c-460b-99b5-88bbbbe86b54' User entered '12 Dec 2020 16:18:06'	System	12 Dec 2020 21:18:09
	System	12 Dec 2020 21:18:09

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-12-18T06:34:56', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7a558cd8-bd15-4e9f-81c2-32d32337b61a' User entered 'Yes (Y)'	System	18 Dec 2020 11:35:56
	System	18 Dec 2020 11:35:56

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Have you been exposed to someone with 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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-12-18T06:34:51', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7a558cd8-bd15-4e9f-81c2-32d32337b61a' User entered 'No (N)'	System	18 Dec 2020 11:35:56
	System	18 Dec 2020 11:35:56

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-12-18T06:34:49', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7a558cd8-bd15-4e9f-81c2-32d32337b61a' User entered 'Yes (Y)'	System	18 Dec 2020 11:35:56
	System	18 Dec 2020 11:35:56

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-12-18T06:34:47', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7a558cd8-bd15-4e9f-81c2-32d32337b61a' User entered '0'	System	18 Dec 2020 11:35:56
	System	18 Dec 2020 11:35:56

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-12-18T06:34:47', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7a558cd8-bd15-4e9f-81c2-32d32337b61a' User entered '0'	System	18 Dec 2020 11:35:56
	System	18 Dec 2020 11:35:56

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-12-18T06:34:47', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7a558cd8-bd15-4e9f-81c2-32d32337b61a' User entered '0'	System	18 Dec 2020 11:35:56
	System	18 Dec 2020 11:35:56

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-12-18T06:34:47', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7a558cd8-bd15-4e9f-81c2-32d32337b61a' User entered '0'	System	18 Dec 2020 11:35:56
	System	18 Dec 2020 11:35:56

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-12-18T06:34:47', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7a558cd8-bd15-4e9f-81c2-32d32337b61a' User entered '0'	System	18 Dec 2020 11:35:56
	System	18 Dec 2020 11:35:56

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-12-18T06:34:47', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7a558cd8-bd15-4e9f-81c2-32d32337b61a' User entered '0'	System	18 Dec 2020 11:35:56
	System	18 Dec 2020 11:35:56

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-12-18T06:34:47', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7a558cd8-bd15-4e9f-81c2-32d32337b61a' User entered '0'	System	18 Dec 2020 11:35:56
	System	18 Dec 2020 11:35:56

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-12-18T06:34:47', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7a558cd8-bd15-4e9f-81c2-32d32337b61a' User entered '0'	System	18 Dec 2020 11:35:56
	System	18 Dec 2020 11:35:56

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-12-18T06:34:47', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7a558cd8-bd15-4e9f-81c2-32d32337b61a' User entered '0'	System	18 Dec 2020 11:35:56
	System	18 Dec 2020 11:35:56

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-12-18T06:34:47', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7a558cd8-bd15-4e9f-81c2-32d32337b61a' User entered '0'	System	18 Dec 2020 11:35:56
	System	18 Dec 2020 11:35:56

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-12-18T06:34:47', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7a558cd8-bd15-4e9f-81c2-32d32337b61a' User entered '0'	System	18 Dec 2020 11:35:56
	System	18 Dec 2020 11:35:56

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-12-18T06:34:47', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7a558cd8-bd15-4e9f-81c2-32d32337b61a' User entered '1'	System	18 Dec 2020 11:35:56
	System	18 Dec 2020 11:35:56

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-12-18T06:34:47', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7a558cd8-bd15-4e9f-81c2-32d32337b61a' User entered '0'	System	18 Dec 2020 11:35:56
	System	18 Dec 2020 11:35:56

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-12-18T06:34:47', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7a558cd8-bd15-4e9f-81c2-32d32337b61a' User entered '0'	System	18 Dec 2020 11:35:56
	System	18 Dec 2020 11:35:56

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-12-18T06:34:47', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7a558cd8-bd15-4e9f-81c2-32d32337b61a' User entered '0'	System	18 Dec 2020 11:35:56
	System	18 Dec 2020 11:35:56

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-12-18T06:34:47', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7a558cd8-bd15-4e9f-81c2-32d32337b61a' User entered '0'	System	18 Dec 2020 11:35:56
	System	18 Dec 2020 11:35:56

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-12-18T06:34:47', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7a558cd8-bd15-4e9f-81c2-32d32337b61a' User entered '0'	System	18 Dec 2020 11:35:56
	System	18 Dec 2020 11:35:56

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-12-18T06:34:37', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7a558cd8-bd15-4e9f-81c2-32d32337b61a'	System	18 Dec 2020 11:35:56
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Dec 2020 11:35:56

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-12-18T06:35:11', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7a558cd8-bd15-4e9f-81c2-32d32337b61a' User entered 'No (N)'	System	18 Dec 2020 11:35:56
	System	18 Dec 2020 11:35:56

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-12-18T06:35:46', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7a558cd8-bd15-4e9f-81c2-32d32337b61a' User entered '18 Dec 2020 06:35:46'	System	18 Dec 2020 11:35:56
	System	18 Dec 2020 11:35:56

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-12-25T00:01:54', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'da70d795-3b6e-45ed-b827-905014fbfc5c' User entered 'No (N)'	System	25 Dec 2020 05:02:26
	System	25 Dec 2020 05:02:26

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Have you been exposed to someone with 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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-12-25T00:02:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'da70d795-3b6e-45ed-b827-905014fbfc5c' User entered 'No (N)'	System	25 Dec 2020 05:02:26
	System	25 Dec 2020 05:02:26

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2020-12-25T00:02:13', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'da70d795-3b6e-45ed-b827-905014fbfc5c' User entered '25 Dec 2020 00:02:13'	System	25 Dec 2020 05:02:26
	System	25 Dec 2020 05:02:26

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-01-01T03:27:24', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '75698de5-5a7a-439c-ae3a-5ffb496367f4'	System	01 Jan 2021 08:27:36
User entered 'No (N)'	System	01 Jan 2021 08:27:36

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

Have you been exposed to someone with 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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-01-01T03:27:28', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '75698de5-5a7a-439c-ae3a-5ffb496367f4' User entered 'No (N)'	System	01 Jan 2021 08:27:36
	System	01 Jan 2021 08:27:36

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-01-01T03:27:32', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '75698de5-5a7a-439c-ae3a-5ffb496367f4' User entered '01 Jan 2021 03:27:32'	System	01 Jan 2021 08:27:36
	System	01 Jan 2021 08:27:36

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-01-08T04:51:18', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'c6348d3d-fbbd-47f4-b2a4-1547b96b84ae' User entered 'No (N)'	System	08 Jan 2021 09:51:39
	System	08 Jan 2021 09:51:39

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

Have you been exposed to someone with 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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-01-08T04:51:27', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'c6348d3d-fbbd-47f4-b2a4-1547b96b84ae'	System	08 Jan 2021 09:51:39
User entered 'No (N)'	System	08 Jan 2021 09:51:39

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-01-08T04:51:37', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'c6348d3d-fbbd-47f4-b2a4-1547b96b84ae' User entered '08 Jan 2021 04:51:37'	System	08 Jan 2021 09:51:39
	System	08 Jan 2021 09:51:39

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-01-15T08:11:22', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'ef809731-cb29-45e2-874d-38a7fbdd0e11' User entered 'No (N)'	System	15 Jan 2021 13:11:44
	System	15 Jan 2021 13:11:44

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Have you been exposed to someone with 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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-01-15T08:11:34', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'ef809731-cb29-45e2-874d-38a7fbdd0e11'	System	15 Jan 2021 13:11:44
User entered 'No (N)'	System	15 Jan 2021 13:11:44

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-01-15T08:11:42', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'ef809731-cb29-45e2-874d-38a7fbdd0e11' User entered '15 Jan 2021 08:11:42'	System	15 Jan 2021 13:11:44
	System	15 Jan 2021 13:11:44

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-01-30T06:07:15', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'd033ea48-57ed-489d-aa92-8e009ec0f372'	System	30 Jan 2021 11:07:37
User entered 'No (N)'	System	30 Jan 2021 11:07:37

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Have you been exposed to someone with 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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-01-30T06:07:24', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'd033ea48-57ed-489d-aa92-8e009ec0f372'	System	30 Jan 2021 11:07:37
User entered 'No (N)'	System	30 Jan 2021 11:07:37

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-01-30T06:07:32', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'd033ea48-57ed-489d-aa92-8e009ec0f372' User entered '30 Jan 2021 06:07:32'	System	30 Jan 2021 11:07:37
	System	30 Jan 2021 11:07:37

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-02-09T11:47:58', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '33bc14b9-b5c2-4a30-9fd2-602659f74dd5' User entered 'No (N)'	System	09 Feb 2021 16:50:12
	System	09 Feb 2021 16:50:12

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Have you been exposed to someone with 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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-02-09T11:48:19', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '33bc14b9-b5c2-4a30-9fd2-602659f74dd5' User entered 'Yes (Y)'	System	09 Feb 2021 16:50:12
	System	09 Feb 2021 16:50:12

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-02-09T11:48:28', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '33bc14b9-b5c2-4a30-9fd2-602659f74dd5'	System	09 Feb 2021 16:50:12
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Feb 2021 16:50:12

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-02-09T11:50:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '33bc14b9-b5c2-4a30-9fd2-602659f74dd5' User entered '09 Feb 2021 11:50:00'	System	09 Feb 2021 16:50:12
	System	09 Feb 2021 16:50:12

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-02-20T08:52:56', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'd7a1cf71-2754-4bf0-ae48-7b9995fc307d' User entered 'Yes (Y)'	System	20 Feb 2021 13:53:42
	System	20 Feb 2021 13:53:42

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

Have you been exposed to someone with 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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-02-20T08:53:01', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'd7a1cf71-2754-4bf0-ae48-7b9995fc307d' User entered 'No (N)'	System	20 Feb 2021 13:53:42

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-02-20T08:53:09', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'd7a1cf71-2754-4bf0-ae48-7b9995fc307d' User entered 'No (N)'	System	20 Feb 2021 13:53:42

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-02-20T08:53:19', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'd7a1cf71-2754-4bf0-ae48-7b9995fc307d' User entered 'Yes (Y)'	System	20 Feb 2021 13:53:42

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-02-20T08:53:27', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'd7a1cf71-2754-4bf0-ae48-7b9995fc307d'	System	20 Feb 2021 13:53:42
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Feb 2021 13:53:42

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-02-20T08:53:33', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'd7a1cf71-2754-4bf0-ae48-7b9995fc307d' User entered '20 Feb 2021 08:53:33'	System	20 Feb 2021 13:53:42
	System	20 Feb 2021 13:53:42

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-02-26T09:30:10-05:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '738b4a55-7d3f-46e3-994e-99657afca63c'	System	26 Feb 2021 14:31:20
User entered 'Yes (Y)'	System	26 Feb 2021 14:31:20

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Have you been exposed to someone with 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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-02-26T09:30:18-05:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '738b4a55-7d3f-46e3-994e-99657afca63c' User entered 'No (N)'	System	26 Feb 2021 14:31:20
	System	26 Feb 2021 14:31:20

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-02-26T09:30:24-05:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '738b4a55-7d3f-46e3-994e-99657afca63c' User entered 'No (N)'	System	26 Feb 2021 14:31:20
	System	26 Feb 2021 14:31:20

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-02-26T09:30:42-05:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '738b4a55-7d3f-46e3-994e-99657afca63c'	System	26 Feb 2021 14:31:20
User entered 'Yes (Y)'	System	26 Feb 2021 14:31:20

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-02-26T09:30:53-05:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '738b4a55-7d3f-46e3-994e-99657afca63c'	System	26 Feb 2021 14:31:20
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Feb 2021 14:31:20

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-02-26T09:31:04-05:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '738b4a55-7d3f-46e3-994e-99657afca63c'	System	26 Feb 2021 14:31:20
User entered '26 Feb 2021 14:31:04'	System	26 Feb 2021 14:31:20

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-03-09T11:37:30-05:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '26ac50e7-920a-4c23-a184-9f4fe11f9a50'	System	09 Mar 2021 16:37:50
User entered 'No (N)'	System	09 Mar 2021 16:37:50

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

Have you been exposed to someone with 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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-03-09T11:37:40-05:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '26ac50e7-920a-4c23-a184-9f4fe11f9a50'	System	09 Mar 2021 16:37:50
User entered 'No (N)'	System	09 Mar 2021 16:37:50

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-03-09T11:37:45-05:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '26ac50e7-920a-4c23-a184-9f4fe11f9a50'	System	09 Mar 2021 16:37:50
User entered '09 Mar 2021 11:37:45'	System	09 Mar 2021 16:37:50

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-03-12T13:12:17-05:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '0ab20e2b-f72d-4aba-bd9f-baba1d8436b4'	System	12 Mar 2021 18:12:33
User entered 'No (N)'	System	12 Mar 2021 18:12:33

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

Have you been exposed to someone with 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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-03-12T13:12:22-05:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '0ab20e2b-f72d-4aba-bd9f-baba1d8436b4' User entered 'No (N)'	System	12 Mar 2021 18:12:33
	System	12 Mar 2021 18:12:33

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-03-12T13:12:27-05:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '0ab20e2b-f72d-4aba-bd9f-baba1d8436b4' User entered '12 Mar 2021 13:12:27'	System	12 Mar 2021 18:12:33
	System	12 Mar 2021 18:12:33

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-03-23T09:59:55-04:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '2084dcbd-c68d-48f8-99f5-da7b6914f4de'	System	23 Mar 2021 14:00:41
User entered 'No (N)'	System	23 Mar 2021 14:00:41

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

Have you been exposed to someone with 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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-03-23T10:00:08-04:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '2084dcbd-c68d-48f8-99f5-da7b6914f4de'	System	23 Mar 2021 14:00:41
User entered 'Yes (Y)'	System	23 Mar 2021 14:00:41

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-03-23T10:00:12-04:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '2084dcbd-c68d-48f8-99f5-da7b6914f4de'	System	23 Mar 2021 14:00:41
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Mar 2021 14:00:41

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-03-23T10:00:23-04:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '2084dcbd-c68d-48f8-99f5-da7b6914f4de'	System	23 Mar 2021 14:00:41
User entered '23 Mar 2021 10:00:23'	System	23 Mar 2021 14:00:41

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-03-28T11:02:05-04:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7b8c787f-fa12-4a8b-9564-a6d6a3b23897'	System	28 Mar 2021 15:02:21
User entered 'No (N)'	System	28 Mar 2021 15:02:21

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Have you been exposed to someone with 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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-03-28T11:02:08-04:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7b8c787f-fa12-4a8b-9564-a6d6a3b23897'	System	28 Mar 2021 15:02:21
User entered 'No (N)'	System	28 Mar 2021 15:02:21

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-03-28T11:02:15-04:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7b8c787f-fa12-4a8b-9564-a6d6a3b23897' User entered '28 Mar 2021 11:02:15'	System	28 Mar 2021 15:02:21
	System	28 Mar 2021 15:02:21

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-04-04T13:38:28-04:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'e63e71bb-b1d0-4f8e-8e45-0d2c2b8e80cf' User entered 'No (N)'	System	04 Apr 2021 17:38:38
	System	04 Apr 2021 17:38:38

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

Have you been exposed to someone with 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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-04-04T13:38:32-04:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'e63e71bb-b1d0-4f8e-8e45-0d2c2b8e80cf' User entered 'No (N)'	System	04 Apr 2021 17:38:38

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-04-04T13:38:36-04:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'e63e71bb-b1d0-4f8e-8e45-0d2c2b8e80cf' User entered '04 Apr 2021 13:38:36'	System	04 Apr 2021 17:38:38
	System	04 Apr 2021 17:38:38

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-04-09T09:56:20-04:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'a56b9172-8ef5-4c03-8efd-44a9c82c2fd3'	System	09 Apr 2021 13:57:46
User entered 'No (N)'	System	09 Apr 2021 13:57:46

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Have you been exposed to someone with 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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-04-09T09:57:12-04:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'a56b9172-8ef5-4c03-8efd-44a9c82c2fd3'	System	09 Apr 2021 13:57:46
User entered 'Yes (Y)'	System	09 Apr 2021 13:57:46

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-04-09T09:57:24-04:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'a56b9172-8ef5-4c03-8efd-44a9c82c2fd3'	System	09 Apr 2021 13:57:46
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Apr 2021 13:57:46

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-04-09T09:57:35-04:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: 'a56b9172-8ef5-4c03-8efd-44a9c82c2fd3'	System	09 Apr 2021 13:57:46
User entered '09 Apr 2021 09:57:35'	System	09 Apr 2021 13:57:46

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-04-16T09:52:21-04:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7bd3eb36-8a7d-4b7e-bc8f-dea37bd39f53'	System	16 Apr 2021 13:52:46
User entered 'No (N)'	System	16 Apr 2021 13:52:46

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Have you been exposed to someone with 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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-04-16T09:52:24-04:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7bd3eb36-8a7d-4b7e-bc8f-dea37bd39f53' User entered 'No (N)'	System	16 Apr 2021 13:52:46
	System	16 Apr 2021 13:52:46

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-04-16T09:52:43-04:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '7bd3eb36-8a7d-4b7e-bc8f-dea37bd39f53'	System	16 Apr 2021 13:52:46
User entered '16 Apr 2021 09:52:43'	System	16 Apr 2021 13:52:46

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-05-01T08:35:06-04:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '55bd758a-b7e6-4e83-bbe1-49eb1c90082d'	System	01 May 2021 12:35:17
User entered 'No (N)'	System	01 May 2021 12:35:17

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Have you been exposed to someone with 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 (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-05-01T08:35:10-04:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '55bd758a-b7e6-4e83-bbe1-49eb1c90082d'	System	01 May 2021 12:35:17
User entered 'No (N)'	System	01 May 2021 12:35:17

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-05-01T08:35:16-04:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '55bd758a-b7e6-4e83-bbe1-49eb1c90082d'	System	01 May 2021 12:35:17
User entered '01 May 2021 08:35:16'	System	01 May 2021 12:35:17

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 02:41:01

US3122090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:23:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:41:01
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 02:41:01

US3122090

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:23:12

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)	30 Apr 2021 11:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-03-02T08:15:55-05:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '57c650e4-745f-48ac-94a5-f075991496b6'	System	02 Mar 2021 13:16:09
User entered 'No (N)'	System	02 Mar 2021 13:16:09

US3122090

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:23:12

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0207C4D0-B5B4-4596-994F-42AFFB9BA6F7)', Time: '2021-03-02T08:16:04-05:00', User OID: 'PatientReportedOutcome (US3122090)', ODM File OID: '57c650e4-745f-48ac-94a5-f075991496b6' User entered '02 Mar 2021 08:16:04'	System	02 Mar 2021 13:16:09
	System	02 Mar 2021 13:16:09

US3122090

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:31:50

US3122090

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '21 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:31:50

US3122090

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:31:50

US3122090

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:31:50

US3122090

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:31:54

US3122090

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:52:01
User entered 'I'	System	23 Oct 2020 15:31:54

US3122090

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:40

US3122090

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '17 Nov 2020'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:40

US3122090

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:40

US3122090

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:40

US3122090

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:45

US3122090

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User entered 'I'	System	17 Nov 2020 14:58:45

US3122090

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 20:54:09

US3122090

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4), (b) (6)	04 Jan 2021 19:52:09
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'Contact out of window due to holiday' (Site from System).		04 Jan 2021 16:51:18
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	31 Dec 2020 20:54:09
User entered '31 Dec 2020'	(b) (4), (b) (6)	31 Dec 2020 20:54:09

US3122090

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 20:54:09

US3122090

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 20:54:09

US3122090

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 20:54:14

US3122090

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User entered 'I'	System	31 Dec 2020 20:54:14

US3122090

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 19:43:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:05:32

US3122090

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		17 Mar 2021 06:27:20
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 19:43:11
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with '1st attempt at 10:18 19/Jan/2021. Contact made same day at 15:45 ' (Site from System).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:07:58
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	19 Jan 2021 21:05:32
User entered '19 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 21:05:32

US3122090

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 19:43:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:05:32

US3122090

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 19:43:11
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:05:32

US3122090

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:05:37

US3122090

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User entered 'I'	System	19 Jan 2021 21:05:37

US3122090

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User closed query 'Per CDM: Visit 4 Day 209 and Visit OL-D29 are both dated 10FEB2021, however, Were vital signs assessed?' is not completed at this visit but at OL-D29 'Were vital signs assessed?' is YES and data is present. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor. Please review and update as appropriate.' (Site from DM).		31 Mar 2021 20:18:30
Query 'Per CDM: Visit 4 Day 209 and Visit OL-D29 are both dated 10FEB2021, however, Were vital signs assessed?' is not completed at this visit but at OL-D29 'Were vital signs assessed?' is YES and data is present. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor. Please review and update as appropriate. answered with 'updated' (Site from DM).		30 Mar 2021 13:24:57
User opened query 'Per CDM: Visit 4 Day 209 and Visit OL-D29 are both dated 10FEB2021, however, Were vital signs assessed?' is not completed at this visit but at OL-D29 'Were vital signs assessed?' is YES and data is present. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor. Please review and update as appropriate.' (Site from DM).		30 Mar 2021 06:24:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 19:43:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Mar 2021 19:13:05
User entered 'Yes (Y)' reason for change: Data Entry Error	System	16 Mar 2021 19:13:05
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	16 Mar 2021 19:13:05
User entered empty; reason for change Data Entry Error	System	12 Mar 2021 15:29:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Mar 2021 15:29:21
		12 Mar 2021 15:26:33

US3122090

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 19:43:11
User entered '10 Feb 2021' reason for change: Data Entry Error	(b) (4)	16 Mar 2021 19:13:05
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 15:29:21
User entered '8 Feb 2021'	(b) (4), (b) (6)	12 Mar 2021 15:26:33

US3122090

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 19:43:11
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:13:05
User entered empty; reason for change Data Entry Error		12 Mar 2021 15:29:21
User entered 'Clinic (Clinic)'		12 Mar 2021 15:26:33

US3122090

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User entered 'VISIT4'	System	16 Mar 2021 19:13:05
User entered empty.	System	12 Mar 2021 15:29:21
User entered 'VISIT4'	System	12 Mar 2021 15:26:33

US3122090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 13:55:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:24:46

US3122090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 13:55:02
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:24:46

US3122090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 13:55:02
User entered '08:55'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:24:46

US3122090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User entered '10 Feb 2021 08:55'	System	30 Mar 2021 13:24:46

US3122090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 13:55:02
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:24:46

US3122090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 13:55:02
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:24:46

US3122090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 13:55:02
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:24:46

US3122090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 13:55:02
User entered '68'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:24:46

US3122090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User entered 'bpm'	System	30 Mar 2021 13:24:46

US3122090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 13:55:02
User entered '16'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:24:46

US3122090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User entered 'breaths/min'	System	30 Mar 2021 13:24:46

US3122090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 13:55:02
User entered '120'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:24:46

US3122090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User entered 'mmHg'	System	30 Mar 2021 13:24:46

US3122090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 13:55:02
User entered '73'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:24:46

US3122090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User entered 'mmHg'	System	30 Mar 2021 13:24:46

US3122090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41

US3122090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41

US3122090

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:23:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 19:43:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Mar 2021 19:13:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Mar 2021 19:13:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 19:13:18
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Mar 2021 15:29:44
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 15:29:44
User entered 'Yes (Y)'		12 Mar 2021 15:26:52

US3122090

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:23:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 19:43:11
User entered '10 Feb 2021' reason for change: Data Entry Error	(b) (4)	16 Mar 2021 19:13:18
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 15:29:44
User entered '8 Feb 2021'	(b) (4), (b) (6)	12 Mar 2021 15:26:52

US3122090

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 19:43:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Mar 2021 19:13:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Mar 2021 19:13:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 19:13:45
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Mar 2021 15:30:04
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 15:30:04
User entered 'No (N)'		12 Mar 2021 15:27:52

US3122090

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 19:43:11
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 15:27:52

US3122090

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:12

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 19:43:11
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 15:27:52

US3122090

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User entered empty.	System	12 Mar 2021 15:27:52

US3122090

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 19:43:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Mar 2021 19:13:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Mar 2021 19:13:50
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 19:13:50
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Mar 2021 15:30:10
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 15:30:10
User entered 'Yes (Y)'		12 Mar 2021 15:28:00

US3122090

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:41
User entered '1'	System	16 Mar 2021 19:13:50
User entered empty.	System	12 Mar 2021 15:30:10
User entered '1'	System	12 Mar 2021 15:28:00

US3122090

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:54:45
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:44:41

US3122090

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:54:45
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:14
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:44:41

US3122090

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:54:45
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:44:41

US3122090

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:54:45
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:14
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:44:41

US3122090

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:54:45
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:44:45

US3122090

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:54:45
User entered 'I'	System	23 Mar 2021 19:44:45

US3122090

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:57:30

US3122090

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:27
User entered '20 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:57:30

US3122090

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:57:30

US3122090

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:27
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:57:30

US3122090

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:27
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Apr 2021 19:57:37

US3122090

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Apr 2021 19:57:37

US3122090

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

Form: Visit Date

Generated On: 09 Jun 2021 15:23:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:20:26

US3122090

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

Form: Visit Date

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:20:26

US3122090

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

Form: Visit Date

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:20:26

US3122090

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

Form: Visit Date

Generated On: 09 Jun 2021 15:23:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered 'UNBLND_DECIDE'	System	12 Jan 2021 15:20:26

US3122090

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

Form: Unblinding

Generated On: 09 Jun 2021 15:23:12

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:20:54

US3122090

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

Form: Unblinding

Generated On: 09 Jun 2021 15:23:12

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	09 Apr 2021 18:47:58
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:54:57
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 10:44:26

US3122090

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

Form: Unblinding

Generated On: 09 Jun 2021 15:23:12

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:20:54

US3122090

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

Form: Unblinding

Generated On: 09 Jun 2021 15:23:12

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM). User signature succeeded.	(b) (4)	15 Apr 2021 11:30:10
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated.' (Site from DM). User entered 'Amendment 6 or later (Amendment 6 or later)' User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM). Amendment Manager inserted this DataPoint.	Matthew Hong (b) (4) (b) (4) (b) (4), (b) (6)	09 Apr 2021 18:47:58 09 Apr 2021 12:55:16 09 Apr 2021 12:54:57 09 Apr 2021 11:31:03
	System	06 Mar 2021 10:44:26

US3122090

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

Form: Unblinding

Generated On: 09 Jun 2021 15:23:12

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:20:54

US3122090

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

Form: Unblinding

Generated On: 09 Jun 2021 15:23:12

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:20:54

US3122090

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

Form: Unblinding

Generated On: 09 Jun 2021 15:23:12

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 05:41:24
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	12 Jan 2021 15:20:54

US3122090

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

Form: Unblinding

Generated On: 09 Jun 2021 15:23:12

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 05:41:24
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	12 Jan 2021 15:20:54

US3122090

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

Form: Unblinding

Generated On: 09 Jun 2021 15:23:12

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:20:54

US3122090

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

Form: Unblinding

Generated On: 09 Jun 2021 15:23:12

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered '1'	System	12 Jan 2021 15:20:54

US3122090

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

Form: Unblinding

Generated On: 09 Jun 2021 15:23:12

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered 'I'	System	12 Jan 2021 15:20:54

US3122090

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:23:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:23:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:23:12

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered empty.	System	12 Jan 2021 15:24:27
DataPoint set to visible.	System	12 Jan 2021 15:20:54

US3122090

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:23:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:23:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:23:12

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered empty.	System	12 Jan 2021 15:24:27
DataPoint set to visible.	System	12 Jan 2021 15:20:54

US3122090

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User accepted default value 'Pre-Dose (PREDOSE)'		12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '08:20'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered '12 Jan 2021 08:20'	System	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '74'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered 'bpm'	System	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '12'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered 'breaths/min'	System	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '120'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered 'mmHg'	System	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '65'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered 'mmHg'	System	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:23:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:23:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:23:12

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered empty.	System	12 Jan 2021 15:24:27
DataPoint set to visible.	System	12 Jan 2021 15:20:54

US3122090

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User accepted default value 'Post-Dose (POSTDOSE)'		12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '10:21'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered '12 Jan 2021 10:21'	System	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '98.8' F	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Oral (Oral)'	(b) (4), (b) (6)	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '64'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered 'bpm'	System	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '18'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered 'breaths/min'	System	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '105'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered 'mmHg'	System	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '76'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:24:27

US3122090

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered 'mmHg'	System	12 Jan 2021 15:24:27

US3122090

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:23:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:24:45

US3122090

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:23:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:24:45

US3122090

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

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:21:29

US3122090

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

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:21:29

US3122090

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

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

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)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:21:29

US3122090

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

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered 'mRNA-1273'	System	12 Jan 2021 15:21:29
DataPoint set to visible.	System	12 Jan 2021 15:20:54

US3122090

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

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:21:29

US3122090

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

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '09:43'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:21:29

US3122090

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

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered '12 Jan 2021 09:43'	System	12 Jan 2021 15:21:29

US3122090

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

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:21:29

US3122090

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

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered 'ONCE'	System	12 Jan 2021 15:21:29

US3122090

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

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered 'INTRAMUSCULAR'	System	12 Jan 2021 15:21:29

US3122090

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:22:34

US3122090

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:22:34

US3122090

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:12

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '08:52'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:22:34

US3122090

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered '12 Jan 2021 08:52'	System	12 Jan 2021 15:22:34

US3122090

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:23:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:22:11

US3122090

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:23:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:22:11

US3122090

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:23:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '08:54'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:22:11

US3122090

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered '12 Jan 2021 08:54'	System	12 Jan 2021 15:22:11

US3122090

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

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:24:52

US3122090

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

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered '1'	System	12 Jan 2021 15:24:52

US3122090

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:05:54

US3122090

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:05:54

US3122090

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:05:54

US3122090

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:05:54

US3122090

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:31:45

US3122090

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered 'I'	System	27 Jan 2021 16:31:45

US3122090

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered '1'	System	27 Jan 2021 16:31:45
DataPoint set to visible.	System	27 Jan 2021 16:31:45

US3122090

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:53:07

US3122090

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:53:07

US3122090

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:53:07

US3122090

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered 'OLD29'	System	10 Feb 2021 15:53:07

US3122090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User accepted default value 'Pre-Dose (PREDOSE)'		10 Feb 2021 15:55:07

US3122090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:55:07

US3122090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:55:07

US3122090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '08:55'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:55:07

US3122090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered '10 Feb 2021 08:55'	System	10 Feb 2021 15:55:07

US3122090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:55:07

US3122090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:55:07

US3122090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:55:07

US3122090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '68'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:55:07

US3122090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered 'bpm'	System	10 Feb 2021 15:55:07

US3122090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '16'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:55:07

US3122090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered 'breaths/min'	System	10 Feb 2021 15:55:07

US3122090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '120'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:55:07

US3122090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered 'mmHg'	System	10 Feb 2021 15:55:07

US3122090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '73'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:55:07

US3122090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:23:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered 'mmHg'	System	10 Feb 2021 15:55:07

US3122090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User accepted default value 'Post-Dose (POSTDOSE)'		10 Feb 2021 15:55:07

US3122090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:55:07

US3122090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:55:07

US3122090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '10:38'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:55:07

US3122090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered '10 Feb 2021 10:38'	System	10 Feb 2021 15:55:07

US3122090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '97.6' F	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:55:07

US3122090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:55:07

US3122090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:55:07

US3122090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '82'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:55:07

US3122090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered 'bpm'	System	10 Feb 2021 15:55:07

US3122090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '16'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:55:07

US3122090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered 'breaths/min'	System	10 Feb 2021 15:55:07

US3122090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '124'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:55:07

US3122090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered 'mmHg'	System	10 Feb 2021 15:55:07

US3122090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '78'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:55:07

US3122090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:23:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered 'mmHg'	System	10 Feb 2021 15:55:07

US3122090

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:23:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:53:28

US3122090

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:23:12

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:53:28

US3122090

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:55:21

US3122090

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:55:21

US3122090

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

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)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:55:21

US3122090

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered 'mRNA-1273'	System	10 Feb 2021 15:55:21
DataPoint set to visible.	System	27 Jan 2021 16:31:45

US3122090

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:55:21

US3122090

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '10:05'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:55:21

US3122090

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered '10 Feb 2021 10:05'	System	10 Feb 2021 15:55:21

US3122090

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:55:21

US3122090

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered 'ONCE'	System	10 Feb 2021 15:55:21

US3122090

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:23:12

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered 'INTRAMUSCULAR'	System	10 Feb 2021 15:55:21

US3122090

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:55:25

US3122090

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered 'I'	System	10 Feb 2021 15:55:25

US3122090

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	10 Mar 2021 18:34:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:38:53

US3122090

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	10 Mar 2021 18:34:36
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:38:53

US3122090

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	10 Mar 2021 18:34:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:38:53

US3122090

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:23:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	10 Mar 2021 18:34:36
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:38:53

US3122090

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	10 Mar 2021 18:34:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:38:59

US3122090

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:23:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered 'I'	System	09 Mar 2021 21:38:59

US3122090

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	23 Mar 2021 19:18:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:01:41

US3122090

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	23 Mar 2021 19:18:02
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:01:41

US3122090

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	23 Mar 2021 19:18:02
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:01:41

US3122090

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:23:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered 'OLD57'	System	23 Mar 2021 19:01:41

US3122090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	23 Mar 2021 19:18:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:02:20

US3122090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	23 Mar 2021 19:18:02
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:02:20

US3122090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	23 Mar 2021 19:18:02
User entered '07:55'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:02:20

US3122090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered '23 Mar 2021 07:55'	System	23 Mar 2021 19:02:20

US3122090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	23 Mar 2021 19:18:02
User entered '36.6' C	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:02:20

US3122090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	23 Mar 2021 19:18:02
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:02:20

US3122090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	23 Mar 2021 19:18:02
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:02:20

US3122090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	23 Mar 2021 19:18:02
User entered '70'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:02:20

US3122090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered 'bpm'	System	23 Mar 2021 19:02:20

US3122090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	23 Mar 2021 19:18:02
User entered '12'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:02:20

US3122090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered 'breaths/min'	System	23 Mar 2021 19:02:20

US3122090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	23 Mar 2021 19:18:02
User entered '132'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:02:20

US3122090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered 'mmHg'	System	23 Mar 2021 19:02:20

US3122090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	23 Mar 2021 19:18:02
User entered '68'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:02:20

US3122090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered 'mmHg'	System	23 Mar 2021 19:02:20

US3122090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36

US3122090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:23:12

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36

US3122090

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:23:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	23 Mar 2021 19:18:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:02:31

US3122090

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:23:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	23 Mar 2021 19:18:02
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:02:31

US3122090

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	23 Mar 2021 19:18:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:02:51

US3122090

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	23 Mar 2021 19:18:02
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:02:51

US3122090

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User signature succeeded.	Matthew Hong (b) (4)	23 Mar 2021 19:18:02
User entered '08:04'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:02:51

US3122090

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:36
User entered '23 Mar 2021 08:04'	System	23 Mar 2021 19:02:51

US3122090

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:23:12

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:34:20
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 13:16:07
User closed query 'Per DM CLR: Per Day 215 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 09:24:46
User closed query 'Per DM CLR: Per Day 208 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.'		12 Apr 2021 09:24:44
' (Site from DM).		
DataPoint Verified.		07 Apr 2021 18:40:06
Query 'Per DM CLR: Per Day 215 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'updated' (Site from DM).		07 Apr 2021 15:53:43

US3122090

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:23:12

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Leah Corts (b) (4) [REDACTED] [REDACTED]	24 Aug 2020 15:23:13

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28
DataPoint Verified.		07 Apr 2021 18:14:25
User coded data point as SOC: Nervous system disorders, HLGT: Cranial nerve disorders (excl neoplasms), HLT: Olfactory nerve disorders, PT: Parosmia, LLT: Altered smell sensation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 00:40:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 00:40:19
User signature succeeded.	Matthew Hong (b) (4) (b) (4)	06 Apr 2021 18:57:26
Data point term sent to Coder	System	06 Apr 2021 17:23:13
User entered 'Altered sense of smell'	(b) (4), (b) (6)	06 Apr 2021 17:22:17

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	06 Apr 2021 18:57:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:22:17

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	06 Apr 2021 18:57:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:22:17

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	06 Apr 2021 18:57:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:22:17

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	06 Apr 2021 18:57:26
User entered '15 Aug 2020'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:22:17

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	06 Apr 2021 18:57:26
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:22:17

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28
User entered empty.	System	06 Apr 2021 17:22:17

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	06 Apr 2021 18:57:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:22:17

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	06 Apr 2021 18:57:26
User entered '1 Sep 2020'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:22:17

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	06 Apr 2021 18:57:26
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:22:17

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28
User entered empty.	System	06 Apr 2021 17:22:17

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	06 Apr 2021 18:57:26
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:22:17

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	06 Apr 2021 18:57:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:22:17

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	06 Apr 2021 18:57:26
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:22:17

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	06 Apr 2021 18:57:26
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:22:17

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	06 Apr 2021 18:57:26
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:22:17

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	06 Apr 2021 18:57:26
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:22:17

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	06 Apr 2021 18:57:26
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:22:17

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	06 Apr 2021 18:57:26
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:22:17

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	06 Apr 2021 18:57:26
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:22:17

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	06 Apr 2021 18:57:26
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:22:17

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	06 Apr 2021 18:57:26
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:22:17

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	06 Apr 2021 18:57:26
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:22:17

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	06 Apr 2021 18:57:26
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:22:17

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	06 Apr 2021 18:57:26
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:22:17

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	06 Apr 2021 18:57:26
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:22:17

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	06 Apr 2021 18:57:26
User entered 'l'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:22:17

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	06 Apr 2021 18:57:26
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:22:17

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	06 Apr 2021 18:57:26
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:22:17

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	06 Apr 2021 18:57:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:22:17

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	06 Apr 2021 18:57:26
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:22:17

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	06 Apr 2021 18:57:26
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:22:17

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28
User entered '0'	System	06 Apr 2021 17:22:17

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28
User entered '0'	System	06 Apr 2021 17:22:17

US3122090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:23:12

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:28

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34
DataPoint Verified.	(b) (4)	07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	06 Apr 2021 20:17:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 20:17:26
Data point term sent to Coder	System	06 Apr 2021 20:15:57
User entered 'headaches'	(b) (4), (b) (6) (b) (4)	06 Apr 2021 20:15:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:15:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:15:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:15:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered '2 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:15:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:15:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34
User entered empty.	System	06 Apr 2021 20:15:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:15:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered '4 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:15:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:15:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34
User entered empty.	System	06 Apr 2021 20:15:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:15:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:15:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:15:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:15:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:15:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:15:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:15:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:15:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:15:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:15:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:15:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:15:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:15:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:15:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:15:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:15:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered 'l'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:15:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:15:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:15:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:15:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:15:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34
User entered '0'	System	06 Apr 2021 20:15:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34
User entered '0'	System	06 Apr 2021 20:15:34

US3122090

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:23:12

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:34

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44
DataPoint Verified.	(b) (4)	07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Stress, LLT: Stress - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 20:18:27
Data point term sent to Coder	(b) (4)	06 Apr 2021 20:18:00
User entered 'stress'	System	06 Apr 2021 20:17:18
	(b) (4), (b) (6)	
	(b) (4)	

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:17:18

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:17:18

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:17:18

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered '2 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:17:18

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:17:18

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44
User entered empty.	System	06 Apr 2021 20:17:18

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:17:18

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered '4 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:17:18

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:17:18

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44
User entered empty.	System	06 Apr 2021 20:17:18

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:17:18

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:17:18

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:17:18

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:17:18

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:17:18

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:17:18

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:17:18

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:17:18

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:17:18

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:17:18

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:17:18

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:17:18

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:17:18

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:17:18

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:17:18

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered 'l'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:17:18

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:17:18

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:17:18

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:17:18

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:17:18

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:17:18

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44
User entered '0'	System	06 Apr 2021 20:17:18

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44
User entered '0'	System	06 Apr 2021 20:17:18

US3122090

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:23:12

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:44

US3122090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:23:12

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 07 Apr 2021 18:14:25
Reviewed for Safety.		07 Apr 2021 14:43:26
User entered	System	07 Apr 2021 14:43:11
'USA-US063-2021-mRNA-1273-P301000002'		
User entered 'New'	(b) (4), (b) (6)	07 Apr 2021 14:43:11

US3122090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:23:12

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:31:12
User signature succeeded.	Matthew Hong (b) (4)	14 Apr 2021 16:51:06
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Synovial and bursal disorders, HLT: Bursal disorders, PT: Bursitis, LLT: Subacromial bursitis - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 14:15:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 14:15:50
Data point term sent to Coder	System	14 Apr 2021 14:15:16
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 14:14:45
Coding entries removed.		14 Apr 2021 14:14:45
Signature has been broken.		14 Apr 2021 14:14:45
User entered 'Subacromial Bursitis' reason for change: Data Entry Error		14 Apr 2021 14:14:45
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Vaccination site reactions, PT: Shoulder injury related to vaccine administration, LLT: Shoulder injury related to vaccine administration - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 20:23:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 20:23:33
Data point term sent to Coder	System	06 Apr 2021 20:22:08
User entered 'SIRVA'	(b) (4), (b) (6)	06 Apr 2021 20:21:07

US3122090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:23:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:21:07

US3122090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:23:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:21:07

US3122090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:23:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:21:07

US3122090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:23:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: As per the narrative section, the subject experienced discomfort 9th day after receiving 2nd vaccine dose. As per the query response the subject started experiencing symptoms 2 days after receiving 2nd dose of vaccination. However the event start date reported is 10 Feb 2021, which is the date the subject received the second dose. Therefore, please reconcile the event start date and update accordingly.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 15:20:53
Query 'PV Query: As per the narrative section, the subject experienced discomfort 9th day after receiving 2nd vaccine dose. As per the query response the subject started experiencing symptoms 2 days after receiving 2nd dose of vaccination. However the event start date reported is 10 Feb 2021, which is the date the subject received the second dose. Therefore, please reconcile the event start date and update accordingly.'		22 Apr 2021 15:38:30
answered with 'Kindly please review the narrative because you are mistaken in your evaluation of it. If you review it you would see that the patient reported the discomfort 9 days after the vaccine not that it started 9 days after. Also, if you continued reading you would have read that the symptoms had started gradually improving by 19FEB2021, which is the 9th day after vaccination and would have been impossible if they didn't start until the the same day.' (Site from Safety).		
User opened query 'PV Query: As per the narrative section, the subject experienced discomfort 9th day after receiving 2nd vaccine dose. As per the query response the subject started experiencing symptoms 2 days after receiving 2nd dose of vaccination. However the event start date reported is 10 Feb 2021, which is the date the subject received the second dose. Therefore, please reconcile the event start date and update accordingly.' (Site from Safety).		22 Apr 2021 12:47:03
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:21:07

US3122090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:23:12

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Apr 2021 20:39:20
User entered '17:00' reason for change: Data Entry Error	System	06 Apr 2021 20:39:20
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	06 Apr 2021 20:21:07
User entered empty.	System	06 Apr 2021 20:21:07

US3122090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:23:12

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '10 Feb 2021 17:00'	System	06 Apr 2021 20:39:20
User entered empty.	System	06 Apr 2021 20:21:07

US3122090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:23:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:27
	(b) (4)	
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	23 Apr 2021 18:18:21
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 18:18:21
Signature has been broken.		23 Apr 2021 18:18:21
User entered 'No (N)' reason for change: Data Entry Error		23 Apr 2021 18:18:21
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	23 Apr 2021 18:17:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Apr 2021 20:21:07

US3122090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:23:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:27
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	23 Apr 2021 18:17:52
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	23 Apr 2021 18:17:52
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 18:17:52
Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 18:17:52
User entered '20 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 18:17:52
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	23 Apr 2021 18:17:28
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 16:13:10
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Subject claims this is still bothering them.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 18:25:34
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 17:16:41
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered empty.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Apr 2021 20:21:07

US3122090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:23:12

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:27
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	23 Apr 2021 18:18:46
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 18:18:46
Signature has been broken.		23 Apr 2021 18:18:46
User entered '00:00' reason for change: Data Entry Error		23 Apr 2021 18:18:46
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Apr 2021 18:18:21
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 20:21:07

US3122090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:23:12

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '20 Apr 2021 00:00'	System	23 Apr 2021 18:18:46
User entered empty.	System	06 Apr 2021 20:21:07

US3122090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:23:12

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:21:07

US3122090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:23:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:21:07

US3122090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:23:12

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:21:07

US3122090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:23:12

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:21:07

US3122090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:23:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:21:07

US3122090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:23:12

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:21:07

US3122090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:23:12

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:21:07

US3122090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:23:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:21:07

US3122090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:23:12

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:21:07

US3122090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:23:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered 'I'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:21:07

US3122090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:23:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:21:07

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Folder: Adverse Events

Form: Adverse Events (5)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:21:07

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:31:12
User signature succeeded.	Matthew Hong (b) (4)	14 Apr 2021 16:51:06
User closed query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug(s). ' (Site from Safety). Query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug(s). ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 16:13:15
DataPoint Un-verified.		12 Apr 2021 18:29:24
Signature has been broken.		12 Apr 2021 18:28:46
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error		12 Apr 2021 18:28:46
User opened query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug(s). ' (Site from Safety).		12 Apr 2021 17:16:17
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered 'Related (RELATED)'	(b) (4), (b) (6)	06 Apr 2021 20:21:07

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Folder: Adverse Events

Form: Adverse Events (5)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study procedure. ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 16:13:24
Query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study procedure. ' answered with 'SIRVA stands for Shoulder injury related to vaccine administration. It started on the day of 2nd dose of vaccine. ' (Site from Safety).		12 Apr 2021 18:31:42
User opened query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study procedure. ' (Site from Safety).		12 Apr 2021 17:16:29
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:21:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:23:12

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:31:12
User signature succeeded.	Matthew Hong (b) (4)	14 Apr 2021 16:51:06
User closed query 'PV Query: As the last dose of mRNA-1273 was given on 10 Feb 2021, please update the action taken with mRNA-1273 from none to not applicable. ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 16:13:29
Query 'PV Query: As the last dose of mRNA-1273 was given on 10 Feb 2021, please update the action taken with mRNA-1273 from none to not applicable. ' answered with 'Updated.' (Site from Safety).		12 Apr 2021 18:25:54
DataPoint Un-verified.		12 Apr 2021 18:24:51
Signature has been broken.		12 Apr 2021 18:24:51
User entered 'Not Applicable (NOT APPLICABLE) reason for change: Data Entry Error		12 Apr 2021 18:24:51
User opened query 'PV Query: As the last dose of mRNA-1273 was given on 10 Feb 2021, please update the action taken with mRNA-1273 from none to not applicable. ' (Site from Safety).		12 Apr 2021 17:16:01
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered 'None (NONE)'	(b) (4), (b) (6)	06 Apr 2021 20:21:07

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Folder: Adverse Events

Form: Adverse Events (5)

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:21:07

US3122090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:23:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 16:13:32
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'ConMed added.' (Site from Safety).		12 Apr 2021 18:49:48
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).		12 Apr 2021 17:16:57
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered 'I'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:21:07

US3122090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:23:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:21:07

US3122090

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:23:12

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 16:02:56
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:27
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 18:18:03
DataPoint Un-verified.		23 Apr 2021 18:17:28
Signature has been broken.		23 Apr 2021 18:17:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error		23 Apr 2021 18:17:28
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).		22 Apr 2021 12:46:40
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).		19 Apr 2021 01:23:36
DataPoint Verified.		16 Apr 2021 18:31:12
User signature succeeded.	Matthew Hong (b) (4)	14 Apr 2021 16:51:06
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'We were asked to ensure all queries have been answered. Will update the outcome soon as we are able to confirm the subject as recovered/resolved' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 14:18:34
DataPoint Un-verified.		12 Apr 2021 18:50:15
Signature has been broken.		12 Apr 2021 18:50:15
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error		12 Apr 2021 18:50:15

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:23:12

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:16:50
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:14:25
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	06 Apr 2021 20:21:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:23:12

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:21:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:23:12

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide further details of course of the event subacromial bursitis.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 15:21:08
Query 'PV Query: Please provide further details of course of the event subacromial bursitis.' answered with 'No further details to submit at this point. ' (Site from Safety).		22 Apr 2021 15:37:03
User opened query 'PV Query: Please provide further details of course of the event subacromial bursitis.' (Site from Safety).		22 Apr 2021 12:47:11
DataPoint Verified.		16 Apr 2021 18:31:12
User closed query 'PV Query: In order to better understand the SAE, please provide a detailed description of the reported shoulder injury and resulting disability, including clinical assessments, diagnostic evaluations, and clinical course. ' (Site from Safety).		15 Apr 2021 15:19:14
User signature succeeded.	Matthew Hong (b) (4)	14 Apr 2021 16:51:06
Query 'PV Query: In order to better understand the SAE, please provide a detailed description of the reported shoulder injury and resulting disability, including clinical assessments, diagnostic evaluations, and clinical course. ' answered with 'updated' (Site from Safety).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:17:22
User entered 'PATIENT PRESENTED FOR EVALUATION OF LEFT SHOULDER. REPORTED DISCOMFORT 9 DAYS AFTER RECEIVING 2ND COVID VACCINE. DESCRIBED PAIN OF THE LATERAL ANTERIOR ASPECT OF LEFT SHOULDER. INITIALLY SYMPTOMS WERE SEVERE AND PREVENTING ANY COMFORTABLE MOTION. HER SYMPTOMS STARTED GRADUALLY IMPROVE BY 19FEB2021. PHYSICAL EXAM WAS DONE AT ORTHO DOCTOR AND THERE ASSESSMENT WAS SUBACROMIAL BURSTITIS OF THE LEFT SHOULDER. She was counseled about conservative care and will continue activity modification.' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 14:17:02
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 14:14:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:23:12

[Narrative](#)

Audit	User	Time (GMT)
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 14:14:45
User entered 'Patient presented wfor evaluation of left shoulder. Reported discomfort 9 days after receiving 2nd COVID vaccine. Described pain pf the lateral anterior aspect of left shoulder. Initially symptoms were severe and preventing any comfortable motion. HER symptoms started gradually improve by 19FEB2021. Physical exam was done at ortho doctor and there assessment was subacromial bursitis of the left shoulder.' reason for change: Data Entry Error		14 Apr 2021 14:14:45
User opened query 'PV Query: In order to better understand the SAE, please provide a detailed description of the reported shoulder injury and resulting disability, including clinical assessments, diagnostic evaluations, and clinical course. ' (Site from Safety).		12 Apr 2021 17:17:07
DataPoint Verified.		07 Apr 2021 18:14:25
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 13:07:55
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 20:21:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:23:12

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 20:21:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:23:12

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 20:21:07

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:34:20
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	13 Aug 2020 15:55:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:24:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 15:13:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	20 Aug 2020 15:13:29
Data point term sent to Coder	System	20 Aug 2020 15:12:13
User entered 'ibuprofen'	Aubrey Farrey (b) (4)	20 Aug 2020 15:11:16
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:24:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'No (N)'	(b) (4) Aubrey Farrray (b) (4) (b) (4)	20 Aug 2020 15:11:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:24:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Migraine'	(b) (4) Aubrey Farrray (b) (4) (b) (4)	20 Aug 2020 15:11:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:24:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '200'	(b) (4) Aubrey Farray (b) (4)	20 Aug 2020 15:11:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:24:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'mg (mg)'	(b) (4) Aubrey Farrah (b) (4) (b) (4)	20 Aug 2020 15:11:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:24:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered empty.	(b) (4) Aubrey Farrah (b) (4)	20 Aug 2020 15:11:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:24:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'as needed (PRN)'	(b) (4) Aubrey Farray (b) (4)	20 Aug 2020 15:11:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:24:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered empty.	(b) (4) Aubrey Farrah (b) (4)	20 Aug 2020 15:11:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:24:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Oral (ORAL)'	(b) (4) Aubrey Farray (b) (4)	20 Aug 2020 15:11:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:24:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered empty.	(b) (4) Aubrey Farray (b) (4)	20 Aug 2020 15:11:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:24:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:12:34
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 15:11:16
User entered 'UN Jan 2020'	Aubrey Farray (b) (4)	20 Aug 2020 15:11:16
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:24:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '0'	Aubrey Farray (b) (4)	20 Aug 2020 15:11:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:24:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'No (N)'	(b) (4) Aubrey Farray (b) (4)	20 Aug 2020 15:11:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:24:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'UN Jun 2020'	Aubrey Farrey (b) (4)	20 Aug 2020 15:11:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:24:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'No (N)'	(b) (4) Aubrey Farrey (b) (4)	20 Aug 2020 15:11:16

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:24:45
User entered empty.	System	20 Aug 2020 15:11:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:24:45
User entered empty.	System	20 Aug 2020 15:11:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:23:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:24:45
User entered empty.	System	20 Aug 2020 15:11:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:12

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Aug 2020 15:14:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 15:14:18
Data point term sent to Coder	System	20 Aug 2020 15:13:14
User entered 'acetaminophen'	Aubrey Farrah (b) (4) (b) (4)	20 Aug 2020 15:12:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
	(b) (4)	
User entered 'No (N)'	Aubrey Farray (b) (4)	20 Aug 2020 15:12:34
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Migraine'	(b) (4) Aubrey Farray (b) (4) (b) (4)	20 Aug 2020 15:12:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Oct 2020 13:14:16
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	Brad Killebrew (b) (4)	01 Oct 2020 19:33:56
User entered '500' reason for change: Data Entry Error	Brad Killebrew (b) (4)	01 Oct 2020 19:33:49
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 07:22:47
User entered '220'	Aubrey Farray (b) (4) (b) (4)	20 Aug 2020 15:12:34

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
	(b) (4)	
User entered 'mg (mg)'	Aubrey Farray (b) (4)	20 Aug 2020 15:12:34
	(b) (4)	

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4) (b) (4)	19 Feb 2021 20:57:15
User entered empty.	Aubrey Farray (b) (4) (b) (4)	20 Aug 2020 15:12:34

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
	(b) (4)	
User entered 'as needed (PRN)'	Aubrey Farray (b) (4)	20 Aug 2020 15:12:34
	(b) (4)	

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered empty.	(b) (4) Aubrey Farray (b) (4) (b) (4)	20 Aug 2020 15:12:34

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Oral (ORAL)'	(b) (4) Aubrey Farray (b) (4) (b) (4)	20 Aug 2020 15:12:34

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered empty.	(b) (4) Aubrey Farrah (b) (4) (b) (4)	20 Aug 2020 15:12:34

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:12:34
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 15:12:34
User entered 'UN Jun 2020'	Aubrey Farray (b) (4)	20 Aug 2020 15:12:34
	(b) (4)	

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '0'	(b) (4) Aubrey Farray (b) (4) (b) (4)	20 Aug 2020 15:12:34

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Yes (Y)'	(b) (4) Aubrey Farray (b) (4) (b) (4)	20 Aug 2020 15:12:34

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
	(b) (4)	
User entered empty.	Aubrey Farray (b) (4)	20 Aug 2020 15:12:34
	(b) (4)	

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'No (N)'	(b) (4) Aubrey Farray (b) (4) (b) (4)	20 Aug 2020 15:12:34

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 15:12:34

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 15:12:34

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:23:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 15:12:34

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:12

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Aug 2020 15:15:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 15:15:22
Data point term sent to Coder	System	20 Aug 2020 15:14:16
User entered 'Magnesium'	Aubrey Farrah (b) (4) (b) (4)	20 Aug 2020 15:13:23

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
	(b) (4)	
User entered 'No (N)'	Aubrey Farrah (b) (4)	20 Aug 2020 15:13:23
	(b) (4)	

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'General Health'	(b) (4) Aubrey Farray (b) (4) (b) (4)	20 Aug 2020 15:13:23

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered '500'	(b) (4) Aubrey Farrah (b) (4) (b) (4)	20 Aug 2020 15:13:23

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'mg (mg)'	(b) (4) Aubrey Farray (b) (4) (b) (4)	20 Aug 2020 15:13:23

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
	(b) (4)	
User entered empty.	Aubrey Farray (b) (4)	20 Aug 2020 15:13:23
	(b) (4)	

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
	(b) (4)	
User entered 'as needed (PRN)'	Aubrey Farray (b) (4)	20 Aug 2020 15:13:23
	(b) (4)	

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
	(b) (4)	
User entered empty.	Aubrey Farray (b) (4)	20 Aug 2020 15:13:23
	(b) (4)	

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
User entered 'Oral (ORAL)'	(b) (4) Aubrey Farrah (b) (4) (b) (4)	20 Aug 2020 15:13:23

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
	(b) (4)	
User entered empty.	Aubrey Farrah (b) (4)	20 Aug 2020 15:13:23
	(b) (4)	

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:12:34
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 15:13:23
User entered 'UN UNK 2010'	Aubrey Farray (b) (4)	20 Aug 2020 15:13:23
	(b) (4)	

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
	(b) (4)	
User entered '0'	Aubrey Farray (b) (4)	20 Aug 2020 15:13:23
	(b) (4)	

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
	(b) (4)	
User entered 'Yes (Y)'	Aubrey Farray (b) (4)	20 Aug 2020 15:13:23
	(b) (4)	

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
	(b) (4)	
User entered empty.	Aubrey Farray (b) (4)	20 Aug 2020 15:13:23
	(b) (4)	

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:57:15
	(b) (4)	
User entered 'No (N)'	Aubrey Farray (b) (4)	20 Aug 2020 15:13:23
	(b) (4)	

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 15:13:23

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 15:13:23

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:23:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 15:13:23

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
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.	Coder Import (b) (4) (b) (4)	12 Apr 2021 19:46:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 19:46:20
User signature succeeded.	Matthew Hong (b) (4) (b) (4)	12 Apr 2021 19:28:40
Data point term sent to Coder	System	12 Apr 2021 18:32:35
User entered 'Tylenol'	(b) (4), (b) (6)	12 Apr 2021 18:32:19

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:32:19

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered 'Injection site pain'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:32:19

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered '250'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:32:19

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:32:19

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:12

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:32:19

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:32:19

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:32:19

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:32:19

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:12

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:32:19

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:32:19

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:32:19

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:32:19

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:32:19

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:32:19

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
User entered empty.	System	12 Apr 2021 18:32:19

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
User entered empty.	System	12 Apr 2021 18:32:19

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:23:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
User entered empty.	System	12 Apr 2021 18:32:19

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:12

[Name of Medication](#)

Audit	User	Time (GMT)
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.	Coder Import (b) (4) (b) (4)	12 Apr 2021 19:46:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 19:46:44
User signature succeeded.	Matthew Hong (b) (4) (b) (4)	12 Apr 2021 19:28:40
Data point term sent to Coder	System	12 Apr 2021 18:34:40
User entered 'Tylenol'	(b) (4), (b) (6) (b) (4)	12 Apr 2021 18:34:27

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:34:27

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered 'Arm Pain'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:34:27

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered '1000'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:34:27

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:34:27

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:34:27

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:34:27

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:34:27

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:34:27

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:34:27

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:34:27

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:34:27

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:34:27

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:34:27

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:34:27

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 18:34:27

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 18:34:27

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:23:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 18:34:27

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:12

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 11:07:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 11:07:46
User signature succeeded.	Matthew Hong (b) (4) (b) (4)	12 Apr 2021 19:28:40
Data point term sent to Coder	System	12 Apr 2021 18:41:55
User entered 'Ibuprofen'	(b) (4), (b) (6) (b) (4)	12 Apr 2021 18:41:16

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:41:16

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered 'ARm pain (sirva)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:41:16

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered '1000'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:41:16

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:41:16

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:41:16

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:41:16

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:41:16

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:41:16

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:41:16

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:12

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

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:41:16

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:41:16

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:41:16

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:41:16

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Apr 2021 19:28:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:41:16

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 18:41:16

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 18:41:16

US3122090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:23:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 18:41:16

US3122090

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:23:12

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:23:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:22:38

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'USA-US063-2021-MRNA-1273-P301000002'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'Yes (Y)'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'No (N)'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'No (N)'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'No (N)'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'Yes (Y)'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'No (N)'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'No (N)'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'Wayne'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'Harper'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered '3100 Duraleigh Rd'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'Raleigh'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'NC'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered '27612'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:13:46
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
User entered 'US'	System	07 Apr 2021 14:44:00

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	26 Apr 2021 16:03:14
User entered '3'	System	15 Apr 2021 15:19:42
User entered '2'	System	13 Apr 2021 16:14:05
User entered '1'	System	07 Apr 2021 14:44:00

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered	System	07 Apr 2021 14:43:11
'USA-US063-2021-MRNA-1273-P301000002'		

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'Yes (Y)'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'No (N)'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'No (N)'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'No (N)'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'Yes (Y)'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'No (N)'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'No (N)'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'Wayne'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'Harper'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered '3100 Duraleigh Rd'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4)	07 Apr 2021 18:13:53
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:43:56
User entered 'Raleigh'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'NC'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered '27612'		07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:13:46
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
User entered 'US'	System	07 Apr 2021 14:44:00

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	26 Apr 2021 16:03:14
User entered '3'	System	15 Apr 2021 15:19:42
User entered '2'	System	13 Apr 2021 16:14:05
User entered '1'	System	07 Apr 2021 14:44:00

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:23:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:13:53
User entered '07/Apr/2021 14:43'	System	07 Apr 2021 14:44:00

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:23:12

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)	13 Apr 2021 16:13:46
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:13:53
User entered 'I'		07 Apr 2021 14:44:00

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'USA-US063-2021-MRNA-1273-P301000002'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'Yes (Y)'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'No (N)'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'No (N)'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'No (N)'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'Yes (Y)'		07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4)	07 Apr 2021 18:13:53
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:43:56
User entered 'No (N)'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'No (N)'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'Wayne'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'Harper'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered '3100 Duraleigh Rd'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'Raleigh'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'NC'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered '27612'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:13:46
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
User entered 'US'	System	07 Apr 2021 14:44:00

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	26 Apr 2021 16:03:14
User entered '3'	System	15 Apr 2021 15:19:42
User entered '2'	System	13 Apr 2021 16:14:05
User entered '1'	System	07 Apr 2021 14:44:00

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:23:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:30:40
User signature succeeded.	Matthew Hong (b) (4)	13 Apr 2021 18:00:52
User entered '13/Apr/2021 12:14'	(b) (4) System	13 Apr 2021 16:14:05

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:23:12

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:30:41
Reviewed for Safety.		15 Apr 2021 15:19:46
User signature succeeded.	Matthew Hong (b) (4)	13 Apr 2021 18:00:52
User entered 'I'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:14:05

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered	System	07 Apr 2021 14:43:11
'USA-US063-2021-MRNA-1273-P301000002'		

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'Yes (Y)'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'No (N)'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'No (N)'		07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'No (N)'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'Yes (Y)'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'No (N)'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'No (N)'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'Wayne'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'Harper'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4)	07 Apr 2021 18:13:53
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:43:56
User entered '3100 Duraleigh Rd'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'Raleigh'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'NC'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered '27612'		07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:13:46
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:13:53
User entered 'US'	System	07 Apr 2021 14:44:00

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	26 Apr 2021 16:03:14
User entered '3'	System	15 Apr 2021 15:19:42
User entered '2'	System	13 Apr 2021 16:14:05
User entered '1'	System	07 Apr 2021 14:44:00

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:23:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:30:49
User signature succeeded.	Matthew Hong (b) (4)	15 Apr 2021 19:15:48
User entered '15/Apr/2021 11:19'	(b) (4) System	15 Apr 2021 15:19:42

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:23:12

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:30:51
User signature succeeded.	Matthew Hong (b) (4)	15 Apr 2021 19:15:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:19:46
User entered 'I'		15 Apr 2021 15:19:42

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'USA-US063-2021-MRNA-1273-P301000002'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'Yes (Y)'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'No (N)'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'No (N)'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'No (N)'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'Yes (Y)'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'No (N)'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'No (N)'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'Wayne'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'Harper'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered '3100 Duraleigh Rd'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4)	07 Apr 2021 18:13:53
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:43:56
User entered 'Raleigh'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered 'NC'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	07 Apr 2021 18:13:53
Reviewed for Safety.		07 Apr 2021 14:43:56
User entered '27612'	System	07 Apr 2021 14:43:11

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:13:46
User signature succeeded.	Matthew Hong (b) (4)	07 Apr 2021 18:49:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:13:53
User entered 'US'	System	07 Apr 2021 14:44:00

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:23:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	26 Apr 2021 16:03:14
User entered '3'	System	15 Apr 2021 15:19:42
User entered '2'	System	13 Apr 2021 16:14:05
User entered '1'	System	07 Apr 2021 14:44:00

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:23:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 16:57:10
User entered '26/Apr/2021 12:03'	(b) (4) System	26 Apr 2021 16:03:14

US3122090

Folder: SAE USA-US063-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:23:12

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.	Matthew Hong (b) (4)	26 Apr 2021 16:57:10
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 16:03:19
User entered 'I'		26 Apr 2021 16:03:14