

US3542090 (Prod: George Washington University)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:36:08

All time stamps listed in this document are displayed in GMT

US3542090

Form: Participant Creation

Data signed: (b) (4) 05 Sep 2020 21:32:59

Generated On: 26 Nov 2020 09:36:08

[Participant ID](#)

US3542090

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

US3542090

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Sep 2020 21:33:29

Generated On: 26 Nov 2020 09:36:08

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	28 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Sep 2020 21:33:29

Generated On: 26 Nov 2020 09:36:08

Date of Birth (MMM yyyy)	(b) (6) 1955
Age	65
Age Units	YEARS
Age (Derived)	65
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☒ Not Hispanic or Latino ☐ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 05 Sep 2020 21:33:29

Generated On: 26 Nov 2020 09:36:08

Date of Informed Consent (<i>dd MMM yyyy</i>)	28 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☐
	Amendment 3 ☒
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 05 Sep 2020 21:33:29

Generated On: 26 Nov 2020 09:36:08

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 05 Sep 2020 21:33:29

Generated On: 26 Nov 2020 09:36:08

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 03 Nov 2020 21:19:52

Generated On: 26 Nov 2020 09:36:08

Condition	SLEEP APNEA
Start date (dd MMM yyyy)	UN AUG 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 03 Nov 2020 21:19:52

Generated On: 26 Nov 2020 09:36:08

Condition	SPINAL SURGERY (L5-S1 FUSION)
Start date (dd MMM yyyy)	UN NOV 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN NOV 2015
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2015
Start Year (derived)	2015
Stop Month and Year (derived)	NOV 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 03 Nov 2020 21:19:52

Generated On: 26 Nov 2020 09:36:08

Condition	PROSTATECTOMY (SECONDARY TO PROSTATE CANCER)
Start date (dd MMM yyyy)	UN AUG 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN AUG 2011
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2011
Start Year (derived)	2011
Stop Month and Year (derived)	AUG 2011
Stop Year (derived)	2011

US3542090

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 03 Nov 2020 21:19:52

Generated On: 26 Nov 2020 09:36:08

Condition	ERECTILE DYSFUNCTION
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	28 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	10:51 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 10:51
Height (<i>xxx.x</i>)	69 in
Weight (<i>xxx.x</i>)	187.8 lb
BMI (<i>xxx.x</i>)	27.79120 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 05 Sep 2020 21:33:29

Generated On: 26 Nov 2020 09:36:08

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Sep 2020 21:33:29

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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

HOUSING INSPECTOR (OFFICE
WORK ONLY AT THIS TIME)

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) 05 Sep 2020 21:33:29

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 05 Sep 2020 21:33:30

Generated On: 26 Nov 2020 09:36:08

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	28 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 20 Nov 2020 04:15:14

Generated On: 26 Nov 2020 09:36:08

What was the date of randomization? (dd MMM yyyy) 28 AUG 2020

What was the participant's randomization number? 188349

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☐
 >=18 and <65 years and at risk ☐
 >=65 years ☒

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m²) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Sep 2020 21:33:30

Generated On: 26 Nov 2020 09:36:08

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Sep 2020 21:33:30

Generated On: 26 Nov 2020 09:36:08

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	28 AUG 2020
Time of assessment (00:00-23:59)	10:51 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 10:51
Temperature (xxx.x)	98.6 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	89 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)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Sep 2020 21:33:30

Generated On: 26 Nov 2020 09:36:08

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	28 AUG 2020
Time of assessment (00:00-23:59)	13:38 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 13:38
Temperature (xxx.x)	98.2 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 05 Sep 2020 21:33:29

Generated On: 26 Nov 2020 09:36:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 05 Sep 2020 21:33:29

Generated On: 26 Nov 2020 09:36:08

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) 28 AUG 2020

What was the treatment time? (00:00-23:59) 13:08 (24 HR)

Treatment Date and Time (derived) 28 AUG 2020 13:08

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Sep 2020 21:33:29

Generated On: 26 Nov 2020 09:36:08

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 AUG 2020

Collection time (00:00-23:59)

11:32 (24 HR)

Collection date and time (derived)

28 AUG 2020 11:32

US3542090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Sep 2020 21:33:29

Generated On: 26 Nov 2020 09:36:08

Collection date (dd MMM yyyy)			28 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:51	28 AUG 2020 11:51
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 05 Sep 2020 21:33:29

Generated On: 26 Nov 2020 09:36:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:08

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

98.2 °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

28 AUG 2020 13:40

PC Open Date & Time

28 AUG 2020 13:28

PC Close Date & Time

28 AUG 2020 15:58

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:08

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 97.7 °F

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

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

PC Time Stamp	28 AUG 2020 18:28
PC Open Date & Time	28 AUG 2020 16:53
PC Close Date & Time	29 AUG 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

29 AUG 2020 12:12

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:08

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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 12:07

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:08

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

31 AUG 2020 17:03

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:08

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 17:53

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:08

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 12:56

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:08

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

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 12:35

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 13:40

PC Open Date & Time

28 AUG 2020 13:28

PC Close Date & Time

28 AUG 2020 15:58

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:08

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

28 AUG 2020 18:29

PC Open Date & Time

28 AUG 2020 16:53

PC Close Date & Time

29 AUG 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:08

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

29 AUG 2020 12:12

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:08

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

30 AUG 2020 12:08

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:08

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

31 AUG 2020 17:04

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:08

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

01 SEP 2020 17:53

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:08

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

02 SEP 2020 12:57

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:08

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

03 SEP 2020 12:36

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:08

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 13:41
PC Open Date & Time	28 AUG 2020 13:28
PC Close Date & Time	28 AUG 2020 15:58

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:08

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 18:30
PC Open Date & Time	28 AUG 2020 16:53
PC Close Date & Time	29 AUG 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:08

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 ☒

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:08

Yes ☐	
PC Time stamp	29 AUG 2020 12:13
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:08

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 ☒

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:08

Yes ☐	
PC Time stamp	30 AUG 2020 12:08
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:08

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 ☒

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:08

Yes ☐	
PC Time stamp	31 AUG 2020 17:05
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:08

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 ☒

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:08

Yes ☐	
PC Time stamp	01 SEP 2020 17:54
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:08

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 ☒

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:08

Yes ☐	
PC Time stamp	02 SEP 2020 12:57
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:08

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 ☒

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:08

Yes ☐	
PC Time stamp	03 SEP 2020 12:36
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 04 SEP 2020 15:46

PC Open Date & Time 04 SEP 2020 12:00

PC Close Date & Time 05 SEP 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

04 SEP 2020 15:47

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 04 SEP 2020 15:47

PC Open Date & Time 04 SEP 2020 12:00

PC Close Date & Time 05 SEP 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 05 SEP 2020 12:45

PC Open Date & Time 05 SEP 2020 12:00

PC Close Date & Time 06 SEP 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 04 SEP 2020 15:47

PC Open Date & Time 04 SEP 2020 12:00

PC Close Date & Time 05 SEP 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 05 SEP 2020 12:45

PC Open Date & Time 05 SEP 2020 12:00

PC Close Date & Time 06 SEP 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp	06 SEP 2020 12:01

PC Open Date & Time	06 SEP 2020 12:00

PC Close Date & Time	07 SEP 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 08 SEP 2020 05:59

PC Open Date & Time 07 SEP 2020 12:00

PC Close Date & Time 08 SEP 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 08 SEP 2020 12:04

PC Open Date & Time 08 SEP 2020 12:00

PC Close Date & Time 09 SEP 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 09 SEP 2020 13:07

PC Open Date & Time 09 SEP 2020 12:00

PC Close Date & Time 10 SEP 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 10 SEP 2020 12:00

PC Open Date & Time 10 SEP 2020 12:00

PC Close Date & Time 11 SEP 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	04 SEP 2020 15:47
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	05 SEP 2020 12:45
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	06 SEP 2020 12:01
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	08 SEP 2020 06:00
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	08 SEP 2020 12:04
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

DAY 13

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

No ☒

Yes ☐

PC Time stamp

09 SEP 2020 13:08

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	10 SEP 2020 12:00
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3542090

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 09 Sep 2020 01:45:22

Generated On: 26 Nov 2020 09:36:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542090

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 09 Sep 2020 01:45:22

Generated On: 26 Nov 2020 09:36:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542090

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 17 Sep 2020 04:22:22

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 17 Sep 2020 04:22:22

Generated On: 26 Nov 2020 09:36:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542090

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 24 Sep 2020 03:14:39

Generated On: 26 Nov 2020 09:36:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542090

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 24 Sep 2020 03:14:39

Generated On: 26 Nov 2020 09:36:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542090

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Oct 2020 18:37:38

Generated On: 26 Nov 2020 09:36:08

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	10 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Oct 2020 18:37:38

Generated On: 26 Nov 2020 09:36:08

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	10 OCT 2020
Time of assessment (00:00-23:59)	13:02 (24 HR)
Vital Signs Date and Time (derived)	10 OCT 2020 13:02
Temperature (xxx.x)	98.2 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Oct 2020 18:37:38

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Oct 2020 18:37:38

Generated On: 26 Nov 2020 09:36:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 OCT 2020

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

US3542090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 14 Oct 2020 04:00:06

Generated On: 26 Nov 2020 09:36:08

Was study treatment given? Yes ☐
No ☒

If No, reason not given

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

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

What was the study treatment?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3542090

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Oct 2020 18:37:38

Generated On: 26 Nov 2020 09:36:08

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	10 OCT 2020
Collection time (00:00-23:59)	13:13 (24 HR)
Collection date and time (derived)	10 OCT 2020 13:13

US3542090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Oct 2020 18:37:38

Generated On: 26 Nov 2020 09:36:08

Collection date (dd MMM yyyy)			10 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:15	10 OCT 2020 13:15
Nasopharyngeal Swab 2	No		

US3542090

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 21 Oct 2020 18:37:38

Generated On: 26 Nov 2020 09:36:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542090

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Nov 2020 21:48:53

Generated On: 26 Nov 2020 09:36:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542090

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Nov 2020 21:48:53

Generated On: 26 Nov 2020 09:36:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542090

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Nov 2020 21:48:53

Generated On: 26 Nov 2020 09:36:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542090

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Nov 2020 21:48:53

Generated On: 26 Nov 2020 09:36:08

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	3 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3542090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	03 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	12:42 (24 HR)
Vital Signs Date and Time (derived)	03 NOV 2020 12:42
Temperature (<i>xxx.x</i>)	98.4 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	76 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3542090

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Nov 2020 21:48:53

Generated On: 26 Nov 2020 09:36:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 NOV 2020

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

US3542090

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Nov 2020 21:48:53

Generated On: 26 Nov 2020 09:36:08

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3542090

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Nov 2020 21:48:53

Generated On: 26 Nov 2020 09:36:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	True
Runny nose	True
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 ☒
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Date and time of submission	01 NOV 2020 19:38:26
Patient Cloud Open Date & Time	28 OCT 2020 00:01
v6.020 DTW (1102)	100 of 1516

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

01 NOV 2020 23:59

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

04 NOV 2020 15:13:20

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

29 OCT 2020 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2020 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2020 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2020 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

DAY 103

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2020 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2020 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

24 DEC 2020 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

Date and time of submission	
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

DAY 138

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

DAY 166

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

DAY 173

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

DAY 187

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

DAY 236

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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°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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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°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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

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14 APR 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

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02 JUN 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

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09 JUN 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

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16 JUN 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

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19 JUN 2022 00:01

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23 JUN 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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 JUN 2022 00:01

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30 JUN 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

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03 JUL 2022 00:01

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07 JUL 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

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10 JUL 2022 00:01

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14 JUL 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

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17 JUL 2022 00:01

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21 JUL 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

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28 JUL 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

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31 JUL 2022 00:01

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04 AUG 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

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07 AUG 2022 00:01

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11 AUG 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

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14 AUG 2022 00:01

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18 AUG 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

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21 AUG 2022 00:01

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25 AUG 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

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28 AUG 2022 00:01

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01 SEP 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 ☐

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3542090

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:08

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3542090

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:36:08

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3542090

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 17 Sep 2020 04:22:22

Generated On: 26 Nov 2020 09:36:08

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

AEID	
Adverse event	RIGHT GROIN PAIN
Was this a medically-attended AE?	Yes ☐ No ☒
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	4 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	4 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	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

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US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

AEID	
Adverse event	POLYARTHRALGIAS
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)	03 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
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	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

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US3542090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Sep 2020 21:33:29

Generated On: 26 Nov 2020 09:36:08

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

Yes ☒

No ☐

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

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Nov 2020 21:48:53

Generated On: 26 Nov 2020 09:36:08

Name of Medication	VITAMIN D
Prophylaxis	Yes ☒ No ☐
Indication	GENERAL HEALTH PROPHYLAXIS
Dose per administration	UNK
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	UNKNOWN
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Nov 2020 21:48:53

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Nov 2020 21:48:53

Generated On: 26 Nov 2020 09:36:08

Name of Medication	VITAMIN C
Prophylaxis	Yes ☒ No ☐
Indication	GENERAL HEALTH PROPHYLAXIS
Dose per administration	UNK
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	UNKNOWN
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Nov 2020 21:48:53

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Nov 2020 21:48:53

Generated On: 26 Nov 2020 09:36:08

Name of Medication	FISH OIL
Prophylaxis	Yes ☒ No ☐
Indication	GENERAL HEALTH PROPHYLAXIS
Dose per administration	UNK
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	UNKNOWN
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Nov 2020 21:48:53

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Nov 2020 21:48:53

Generated On: 26 Nov 2020 09:36:08

Name of Medication GARLIC PILLS

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH
PROPHYLAXIS

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Nov 2020 21:48:53

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Nov 2020 21:48:53

Generated On: 26 Nov 2020 09:36:08

Name of Medication	MULTIVITAMIN
Prophylaxis	Yes ☐ No ☒
Indication	GENERAL HEALTH PROPHYLAXIS
Dose per administration	UNK
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	UNKNOWN
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Nov 2020 21:48:53

Generated On: 26 Nov 2020 09:36:08

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

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Nov 2020 21:48:53

Generated On: 26 Nov 2020 09:36:08

Name of Medication VIAGRA

Prophylaxis Yes ☐
No ☒

Indication ERECTILE DYSFUNCTION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Nov 2020 21:48:53

Generated On: 26 Nov 2020 09:36:08

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUL 2012	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Nov 2020 21:48:53

Generated On: 26 Nov 2020 09:36:08

Name of Medication CYCLOBENZAPRINE

Prophylaxis Yes ☐
No ☒

Indication POLYARTHRALGIAS

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Nov 2020 21:48:53

Generated On: 26 Nov 2020 09:36:08

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Nov 2020 21:48:53

Generated On: 26 Nov 2020 09:36:08

Name of Medication NAPROXEN

Prophylaxis Yes ☐
No ☒

Indication POLYARTHRALGIAS

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 ☐

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Nov 2020 21:48:53

Generated On: 26 Nov 2020 09:36:08

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3542090

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:36:08

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3542090

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 21 Nov 2020 16:51:57

Generated On: 26 Nov 2020 09:36:08

Date of dosing discontinuation (dd MMM yyyy)	10 OCT 2020

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

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	AE #2

US3542090

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:36:08

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 ☐

Audit

US3542090 (Prod: George Washington University)

US3542090

Form: Participant Creation

Generated On: 26 Nov 2020 09:36:08

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:32:59
User entered 'US3542090'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 15:24:48

US3542090

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:36:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:40:43
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'Yes (Y)'	Elissa Malkin (b) (4)	28 Aug 2020 16:14:33
	(b) (4)	

US3542090

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:40:47
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '28 AUG 2020'	RWS_ENDPOINT	28 Aug 2020 15:24:49
	ENDPOINT (b) (4)	

US3542090

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:40:47
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'Clinic (Clinic)'	Elissa Malkin (b) (4)	28 Aug 2020 16:14:33
	(b) (4)	

US3542090

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:36:08

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	28 Aug 2020 16:14:33

US3542090

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:07
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered (b) (6) 1955' reason for change: Data Entry Error	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 15:35:04
User entered (b) (6) 1995'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 15:24:50

US3542090

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:08

[Age](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:07
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '65'	Madhu Balachandran	31 Aug 2020 18:40:18
	(b) (4)	

US3542090

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:08

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	31 Aug 2020 18:40:18

US3542090

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:08

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '65'	System	28 Aug 2020 16:14:49

US3542090

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:08

Sex

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:07
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'Male (M)'	Madhu Balachandran	31 Aug 2020 18:40:18
	(b) (4)	

US3542090

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:08

[Ethnicity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:07
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Madhu Balachandran	31 Aug 2020 18:40:18
	(b) (4)	

US3542090

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:08

[White](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:07
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '1'	Madhu Balachandran	31 Aug 2020 18:40:18
	(b) (4)	

US3542090

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:08

[Black](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:07
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '0'	Madhu Balachandran	31 Aug 2020 18:40:18
	(b) (4)	

US3542090

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:08

[Asian](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:07
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '0'	Madhu Balachandran	31 Aug 2020 18:40:18
	(b) (4)	

US3542090

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:08

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:07
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '0'	Madhu Balachandran	31 Aug 2020 18:40:18
	(b) (4)	

US3542090

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:08

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:07
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '0'	Madhu Balachandran	31 Aug 2020 18:40:18
	(b) (4)	

US3542090

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:08

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:07
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '0'	Madhu Balachandran	31 Aug 2020 18:40:18
	(b) (4)	

US3542090

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:08

[If race is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:07
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered empty.	Madhu Balachandran	31 Aug 2020 18:40:18
	(b) (4)	

US3542090

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:08

Unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:07
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '0'	Madhu Balachandran	31 Aug 2020 18:40:18
	(b) (4)	

US3542090

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:08

[Not reported](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:07
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '0'	Madhu Balachandran	31 Aug 2020 18:40:18
	(b) (4)	

US3542090

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:45
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '28 Aug 2020'	Elissa Malkin (b) (4)	28 Aug 2020 16:14:49
	(b) (4)	

US3542090

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	28 Aug 2020 16:14:49

US3542090

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered '2020'	System	28 Aug 2020 16:14:49

US3542090

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:36:08

[Protocol Version](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:45
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'Amendment 3 (3)'	Elissa Malkin (b) (4)	28 Aug 2020 16:14:49
	(b) (4)	

US3542090

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:45
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'Yes (Y)'	Elissa Malkin (b) (4)	28 Aug 2020 16:14:49
	(b) (4)	

US3542090

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:45
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered empty.	Elissa Malkin (b) (4)	28 Aug 2020 16:14:49
	(b) (4)	

US3542090

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:36:08

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:45
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered empty.	Elissa Malkin (b) (4)	28 Aug 2020 16:14:49
	(b) (4)	

US3542090

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:36:08

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:45
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'No (N)'	Elissa Malkin (b) (4)	28 Aug 2020 16:14:49
	(b) (4)	

US3542090

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:36:08

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:45
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered empty.	RWS_ENDPOINT	28 Aug 2020 15:24:49
	ENDPOINT (b) (4)	

US3542090

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:36:08

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 16:14:55

US3542090

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:45:47
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'Yes (Y)'	Elissa Malkin (b) (4)	28 Aug 2020 16:14:55
	(b) (4)	

US3542090

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:36:08

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:48:13
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'Yes (Y)'	Madhu Balachandran	31 Aug 2020 18:40:51
	(b) (4)	

US3542090

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:36:08

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:58:12
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\23.0.	Coder Import (b) (4)	31 Aug 2020 18:41:38
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	31 Aug 2020 18:41:38
	(b) (4)	
Data point term sent to Coder	System	31 Aug 2020 18:41:15
User entered 'Sleep Apnea'	Madhu Balachandran	31 Aug 2020 18:41:09
	(b) (4)	

US3542090

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:58:12
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'UN Aug 2019'	Madhu Balachandran	31 Aug 2020 18:41:09
	(b) (4)	

US3542090

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:36:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:58:12
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '0'	Madhu Balachandran	31 Aug 2020 18:41:09
	(b) (4)	

US3542090

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:36:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:58:12
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'Yes (Y)'	Madhu Balachandran	31 Aug 2020 18:41:09
	(b) (4)	

US3542090

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:58:12
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered empty.	Madhu Balachandran	31 Aug 2020 18:41:09
	(b) (4)	

US3542090

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:36:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:58:12
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '0'	Madhu Balachandran	31 Aug 2020 18:41:09
	(b) (4)	

US3542090

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered 'Aug 2019'	System	31 Aug 2020 18:41:09

US3542090

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered '2019'	System	31 Aug 2020 18:41:09

US3542090

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 18:41:09

US3542090

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 18:41:09

US3542090

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:36:08

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:58:12
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal fusion surgery, LLT: Spinal fusion surgery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Sep 2020 15:40:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Sep 2020 15:40:50
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
Data point term sent to Coder	System	31 Aug 2020 18:42:19
User entered 'Spinal surgery (L5-S1 Fusion)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:41:44

US3542090

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:58:12
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'UN Nov 2015'	Madhu Balachandran	31 Aug 2020 18:41:44
	(b) (4)	

US3542090

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:36:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:58:12
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '0'	Madhu Balachandran	31 Aug 2020 18:41:44
	(b) (4)	

US3542090

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:36:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:58:12
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'No (N)'	Madhu Balachandran	31 Aug 2020 18:41:44
	(b) (4)	

US3542090

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:58:12
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'UN Nov 2015'	Madhu Balachandran	31 Aug 2020 18:41:44
	(b) (4)	

US3542090

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:36:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:58:12
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '0'	Madhu Balachandran	31 Aug 2020 18:41:44
	(b) (4)	

US3542090

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered 'Nov 2015'	System	31 Aug 2020 18:41:44

US3542090

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered '2015'	System	31 Aug 2020 18:41:44

US3542090

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered 'Nov 2015'	System	31 Aug 2020 18:41:44

US3542090

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered '2015'	System	31 Aug 2020 18:41:44

US3542090

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:36:08

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Prostatic therapeutic procedures, PT: Prostatectomy, LLT: Prostatectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 07:09:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 07:09:51
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:58:12
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
Data point term sent to Coder	System	31 Aug 2020 18:42:22
User entered 'Prostatectomy (secondary to Prostate Cancer)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:42:10

US3542090

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:58:12
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'UN Aug 2011'	Madhu Balachandran	31 Aug 2020 18:42:10
	(b) (4)	

US3542090

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:36:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:58:12
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '0'	Madhu Balachandran	31 Aug 2020 18:42:10
	(b) (4)	

US3542090

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:36:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:58:12
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'No (N)'	Madhu Balachandran	31 Aug 2020 18:42:10
	(b) (4)	

US3542090

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:58:12
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'UN Aug 2011'	Madhu Balachandran	31 Aug 2020 18:42:10
	(b) (4)	

US3542090

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:36:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:58:12
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '0'	Madhu Balachandran	31 Aug 2020 18:42:10
	(b) (4)	

US3542090

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered 'Aug 2011'	System	31 Aug 2020 18:42:10

US3542090

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered '2011'	System	31 Aug 2020 18:42:10

US3542090

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered 'Aug 2011'	System	31 Aug 2020 18:42:10

US3542090

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered '2011'	System	31 Aug 2020 18:42:10

US3542090

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:36:08

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\\23.0.	Coder Import (b) (4)	03 Nov 2020 21:20:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Nov 2020 21:20:25
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:19:52
Data point term sent to Coder	System (b) (4)	03 Nov 2020 21:19:42
User entered 'Erectile dysfunction'	David Diemert (b) (4)	03 Nov 2020 21:19:17

US3542090

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:19:52
	(b) (4)	
User entered 'un UNK 2012'	David Diemert (b) (4)	03 Nov 2020 21:19:17
	(b) (4)	

US3542090

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:36:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:19:52
	(b) (4)	
User entered '0'	David Diemert (b) (4)	03 Nov 2020 21:19:17
	(b) (4)	

US3542090

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:36:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:19:52
	(b) (4)	
User entered 'Yes (Y)'	David Diemert (b) (4)	03 Nov 2020 21:19:17
	(b) (4)	

US3542090

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:19:52
	(b) (4)	
User entered empty.	David Diemert (b) (4)	03 Nov 2020 21:19:17
	(b) (4)	

US3542090

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:36:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:19:52
	(b) (4)	
User entered '0'	David Diemert (b) (4)	03 Nov 2020 21:19:17
	(b) (4)	

US3542090

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	03 Nov 2020 21:19:17

US3542090

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered '2012'	System	03 Nov 2020 21:19:17

US3542090

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 21:19:17

US3542090

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 21:19:17

US3542090

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:00:13
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'Yes (Y)'	Madhu Balachandran	31 Aug 2020 18:42:52
	(b) (4)	

US3542090

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:00:13
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '28 Aug 2020'	Madhu Balachandran	31 Aug 2020 18:42:52
	(b) (4)	

US3542090

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:00:13
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '10:51'	Madhu Balachandran	31 Aug 2020 18:42:52
	(b) (4)	

US3542090

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered '28 Aug 2020 10:51'	System	31 Aug 2020 18:42:52

US3542090

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:00:13
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '69' in	Madhu Balachandran	31 Aug 2020 18:42:52
	(b) (4)	
DataPoint set to visible.	System	28 Aug 2020 16:14:55

US3542090

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:00:13
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '187.8' lb	Madhu Balachandran	31 Aug 2020 18:42:52
	(b) (4)	
DataPoint set to visible.	System	28 Aug 2020 16:14:55

US3542090

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '27.79120'	System	31 Aug 2020 18:42:52
DataPoint set to visible.	System	28 Aug 2020 16:14:55

US3542090

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	31 Aug 2020 18:42:52
DataPoint set to visible.	System	28 Aug 2020 16:14:55

US3542090

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:00:13
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered missing code ND - Not Done.	Madhu Balachandran	31 Aug 2020 18:42:52
	(b) (4)	

US3542090

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:00:13
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered empty.	Madhu Balachandran	31 Aug 2020 18:42:52
	(b) (4)	

US3542090

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:00:13
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered empty.	Madhu Balachandran	31 Aug 2020 18:42:52
	(b) (4)	

US3542090

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:00:13
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered missing code ND - Not Done.	Madhu Balachandran	31 Aug 2020 18:42:52
	(b) (4)	

US3542090

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	31 Aug 2020 18:42:52

US3542090

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:00:13
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered missing code ND - Not Done.	Madhu Balachandran	31 Aug 2020 18:42:52
	(b) (4)	

US3542090

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	31 Aug 2020 18:42:52

US3542090

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:00:13
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered missing code ND - Not Done.	Madhu Balachandran	31 Aug 2020 18:42:52
	(b) (4)	

US3542090

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Aug 2020 18:42:52

US3542090

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:00:13
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered missing code ND - Not Done.	Madhu Balachandran	31 Aug 2020 18:42:52
	(b) (4)	

US3542090

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Aug 2020 18:42:52

US3542090

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:00:51
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'No (N)'	Madhu Balachandran	31 Aug 2020 18:42:55
	(b) (4)	

US3542090

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:08

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:00:51
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered empty.	Madhu Balachandran	31 Aug 2020 18:42:55
	(b) (4)	

US3542090

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:01:23
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'No (N)'	Madhu Balachandran	31 Aug 2020 18:43:36
	(b) (4)	

US3542090

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:01:23
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'No (N)'	Madhu Balachandran	31 Aug 2020 18:43:36
	(b) (4)	

US3542090

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:01:23
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'No (N)'	Madhu Balachandran	31 Aug 2020 18:43:36
	(b) (4)	

US3542090

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:01:23
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'No (N)'	Madhu Balachandran	31 Aug 2020 18:43:36
	(b) (4)	

US3542090

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:01:23
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'No (N)'	Madhu Balachandran	31 Aug 2020 18:43:36
	(b) (4)	

US3542090

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:01:23
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'No (N)'	Madhu Balachandran	31 Aug 2020 18:43:36
	(b) (4)	

US3542090

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:01:23
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'No (N)'	Madhu Balachandran	31 Aug 2020 18:43:36
	(b) (4)	

US3542090

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:01:23
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'No (N)'	Madhu Balachandran	31 Aug 2020 18:43:36
	(b) (4)	

US3542090

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:01:23
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'No (N)'	Madhu Balachandran	31 Aug 2020 18:43:36
	(b) (4)	

US3542090

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:01:23
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'No (N)'	Madhu Balachandran	31 Aug 2020 18:43:36
	(b) (4)	

US3542090

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:01:23
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'No (N)'	Madhu Balachandran	31 Aug 2020 18:43:36
	(b) (4)	

US3542090

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:08

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:01:23
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'Yes (Y)'	Madhu Balachandran	31 Aug 2020 18:43:36
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:08

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:01:23
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'HOUSING INSPECTOR (office work only at this time)' reason for change: Data Entry Error	Hannah Yellin (b) (4)	04 Sep 2020 18:48:28
	(b) (4)	
User entered 'Housing Inspector'	Madhu Balachandran	31 Aug 2020 18:43:36
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:43:36

US3542090

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:01:23
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '0'	Madhu Balachandran	31 Aug 2020 18:43:36
	(b) (4)	

US3542090

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:01:23
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '0'	Madhu Balachandran	31 Aug 2020 18:43:36
	(b) (4)	

US3542090

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:01:23
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '1'	Madhu Balachandran	31 Aug 2020 18:43:36
	(b) (4)	

US3542090

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:01:23
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '0'	Madhu Balachandran	31 Aug 2020 18:43:36
	(b) (4)	

US3542090

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:01:23
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '0'	Madhu Balachandran	31 Aug 2020 18:43:36
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:08

[Other](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:43:36

US3542090

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:08

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:01:23
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered empty.	Madhu Balachandran	31 Aug 2020 18:43:36
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:36:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:42:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'Yes (Y)'	Madhu Balachandran	31 Aug 2020 18:44:25
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:42:39
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '28 Aug 2020'	Madhu Balachandran	31 Aug 2020 18:44:25
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:42:39
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'Clinic (Clinic)'	Madhu Balachandran	31 Aug 2020 18:44:25
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:36:08

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	31 Aug 2020 18:44:25

US3542090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:43:16
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '28 AUG 2020'	RWS_ENDPOINT	28 Aug 2020 16:24:40
	ENDPOINT (b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:45:09
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '188349'	RWS_ENDPOINT	28 Aug 2020 16:24:40
	ENDPOINT (b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:45:09
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '>=65 years (3)'	RWS_ENDPOINT	28 Aug 2020 16:24:40
	ENDPOINT (b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:45:09
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'No (N)'	Madhu Balachandran	31 Aug 2020 18:44:35
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:45:09
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'No (N)'	Madhu Balachandran	31 Aug 2020 18:44:35
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:45:09
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'No (N)'	Madhu Balachandran	31 Aug 2020 18:44:35
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:36:08

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:45:09
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'No (N)'	Madhu Balachandran	31 Aug 2020 18:44:35
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:36:08

[Liver Disease](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:45:09
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'No (N)'	Madhu Balachandran	31 Aug 2020 18:44:35
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:21:06
User closed query 'Please enter data.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 15:38:36
Query 'Please enter data.' answered with 'Data entered' (Site from CRA).	Hannah Yellin (b) (4)	23 Sep 2020 15:02:28
User entered 'No (N)'	(b) (4)	
	Hannah Yellin (b) (4)	23 Sep 2020 15:02:06
	(b) (4)	
User opened query 'Please enter data.' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 13:47:12
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:26:17
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:26:16

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:36:08

Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered missing code ND - Not Done.	Madhu Balachandran	31 Aug 2020 18:46:08
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:36:08

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered missing code ND - Not Done.	Madhu Balachandran	31 Aug 2020 18:46:08
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:36:08

Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered missing code ND - Not Done.	Madhu Balachandran	31 Aug 2020 18:46:08
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:36:08

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered missing code ND - Not Done.	Madhu Balachandran	31 Aug 2020 18:46:08
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:08

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:08

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'Yes (Y)'	Madhu Balachandran	31 Aug 2020 18:46:08
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '28 Aug 2020'	Madhu Balachandran	31 Aug 2020 18:46:08
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '10:51'	Madhu Balachandran	31 Aug 2020 18:46:08
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered '28 Aug 2020 10:51'	System	31 Aug 2020 18:46:08

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:08

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '98.6' F	Madhu Balachandran	31 Aug 2020 18:46:08
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:08

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'Oral (Oral)'	Madhu Balachandran	31 Aug 2020 18:46:08
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:08

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered empty.	Madhu Balachandran	31 Aug 2020 18:46:08
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '89'	Madhu Balachandran	31 Aug 2020 18:46:08
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:08

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	31 Aug 2020 18:46:08

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '16'	Madhu Balachandran	31 Aug 2020 18:46:08
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	31 Aug 2020 18:46:08

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '127'	Madhu Balachandran	31 Aug 2020 18:46:08
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Aug 2020 18:46:08

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '72'	Madhu Balachandran	31 Aug 2020 18:46:08
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Aug 2020 18:46:08

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:36:08

Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered missing code ND - Not Done.	Madhu Balachandran	31 Aug 2020 18:46:08
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:36:08

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered missing code ND - Not Done.	Madhu Balachandran	31 Aug 2020 18:46:08
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:08

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:08

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'Yes (Y)'	Madhu Balachandran	31 Aug 2020 18:46:08
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '28 Aug 2020'	Madhu Balachandran	31 Aug 2020 18:46:08
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '13:38'	Madhu Balachandran	31 Aug 2020 18:46:08
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered '28 Aug 2020 13:38'	System	31 Aug 2020 18:46:08

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:08

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '98.2' F	Madhu Balachandran	31 Aug 2020 18:46:08
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:08

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'Oral (Oral)'	Madhu Balachandran	31 Aug 2020 18:46:08
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:08

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered empty.	Madhu Balachandran	31 Aug 2020 18:46:08
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '70'	Madhu Balachandran	31 Aug 2020 18:46:08
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:08

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	31 Aug 2020 18:46:08

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '16'	Madhu Balachandran	31 Aug 2020 18:46:08
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	31 Aug 2020 18:46:08

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '110'	Madhu Balachandran	31 Aug 2020 18:46:08
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Aug 2020 18:46:08

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '70'	Madhu Balachandran	31 Aug 2020 18:46:08
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Aug 2020 18:46:08

US3542090

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:49:36
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'Yes (Y)'	Madhu Balachandran	31 Aug 2020 18:46:13
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:49:36
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '28 Aug 2020'	Madhu Balachandran	31 Aug 2020 18:46:13
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:36:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:50:18
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'Yes (Y)'	Hira Qadir (b) (4)	28 Aug 2020 17:12:37
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:36:08

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:50:33
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered empty.	Hira Qadir (b) (4)	28 Aug 2020 17:12:37
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:50:33
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered empty.	Hira Qadir (b) (4)	28 Aug 2020 17:12:37
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:36:08

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 17:12:37

US3542090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:36:08

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:50:33
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '28 Aug 2020'	Hira Qadir (b) (4)	28 Aug 2020 17:12:37
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:50:33
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '13:08'	Hira Qadir (b) (4)	28 Aug 2020 17:12:37
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered '28 Aug 2020 13:08'	System	28 Aug 2020 17:12:37

US3542090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:50:33
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'Right Arm (RIGHT ARM)'	Hira Qadir (b) (4)	28 Aug 2020 17:12:37
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:50:33
User entered 'ONCE'	System	28 Aug 2020 17:12:37

US3542090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 17:12:37

US3542090

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:52:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'Yes (Y)'	Madhu Balachandran	31 Aug 2020 18:46:37
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:52:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '28 Aug 2020'	Madhu Balachandran	31 Aug 2020 18:46:37
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:52:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '11:32'	Madhu Balachandran	31 Aug 2020 18:46:37
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:32'	System	31 Aug 2020 18:46:37

US3542090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:36:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:53:04
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '28 Aug 2020'	Madhu Balachandran	31 Aug 2020 18:47:14
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:36:08

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:47:14

US3542090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:36:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:53:06
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'Yes (Y)'	Madhu Balachandran	31 Aug 2020 18:47:14
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:36:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:53:06
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered '11:51'	Madhu Balachandran	31 Aug 2020 18:47:14
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:51'	System	31 Aug 2020 18:47:14

US3542090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:36:08

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:47:14

US3542090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:36:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:53:06
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'No (N)'	Madhu Balachandran	31 Aug 2020 18:47:14
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:36:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:53:06
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered empty.	Madhu Balachandran	31 Aug 2020 18:47:14
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 18:47:14

US3542090

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:53:13
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'Yes (Y)'	Madhu Balachandran	31 Aug 2020 18:47:23
	(b) (4)	

US3542090

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:36:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 18:47:23

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 17:12:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (382e5f362d67230c)', Time: '2020-08-28T13:40:03', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'c027e14d-97da-4b4c-8892-0caf4ae6bb94'	System	28 Aug 2020 17:40:33
User entered 'Yes (Y)'	System	28 Aug 2020 17:40:33

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (382e5f362d67230c)', Time: '2020-08-28T13:40:14', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'c027e14d-97da-4b4c-8892-0caf4ae6bb94'	System	28 Aug 2020 17:40:33
User entered '98.2'	System	28 Aug 2020 17:40:33

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (382e5f362d67230c)', Time: '2020-08-28T13:40:20', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'c027e14d-97da-4b4c-8892-0caf4ae6bb94'	System	28 Aug 2020 17:40:33
User entered 'No (N)'	System	28 Aug 2020 17:40:33

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (382e5f362d67230c)', Time: '2020-08-28T13:40:26', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'c027e14d-97da-4b4c-8892-0caf4ae6bb94'	System	28 Aug 2020 17:40:33
User entered '28 Aug 2020 13:40'	System	28 Aug 2020 17:40:33

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 13:28'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 15:58'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 17:12:37
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (382e5f362d67230c)', Time: '2020-08-28T18:24:45', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '9a963ce8-be0d-4ce3-8f79-da86479f2d65'	System	28 Aug 2020 22:28:22
User entered 'Yes (Y)'	System	28 Aug 2020 22:28:22

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (382e5f362d67230c)', Time: '2020-08-28T18:28:03', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '9a963ce8-be0d-4ce3-8f79-da86479f2d65'	System	28 Aug 2020 22:28:22
User entered '97.7'	System	28 Aug 2020 22:28:22

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (382e5f362d67230c)', Time: '2020-08-28T18:28:08', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '9a963ce8-be0d-4ce3-8f79-da86479f2d65'	System	28 Aug 2020 22:28:22
User entered 'No (N)'	System	28 Aug 2020 22:28:22

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (382e5f362d67230c)', Time: '2020-08-28T18:28:19', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '9a963ce8-be0d-4ce3-8f79-da86479f2d65'	System	28 Aug 2020 22:28:22
User entered '28 Aug 2020 18:28'	System	28 Aug 2020 22:28:22

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 16:53'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 17:12:37
User entered 'Day 2'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-29T12:12:09', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '48a8a893-989f-42fa-b7f4-3cc01f8712f6'	System	29 Aug 2020 16:12:25
User entered 'Yes (Y)'	System	29 Aug 2020 16:12:25

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-29T12:12:15', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '48a8a893-989f-42fa-b7f4-3cc01f8712f6'	System	29 Aug 2020 16:12:25
User entered '98.0'	System	29 Aug 2020 16:12:25

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-29T12:12:18', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '48a8a893-989f-42fa-b7f4-3cc01f8712f6'	System	29 Aug 2020 16:12:25
User entered 'No (N)'	System	29 Aug 2020 16:12:25

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-29T12:12:23', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '48a8a893-989f-42fa-b7f4-3cc01f8712f6'	System	29 Aug 2020 16:12:25
User entered '29 Aug 2020 12:12'	System	29 Aug 2020 16:12:25

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 17:12:37
User entered 'Day 3'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-30T12:07:06', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '485a7abb-b139-45f2-a149-86637ee7cf27'	System	30 Aug 2020 16:07:45
User entered 'Yes (Y)'	System	30 Aug 2020 16:07:45

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-30T12:07:19', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '485a7abb-b139-45f2-a149-86637ee7cf27'	System	30 Aug 2020 16:07:45
User entered '97.2'	System	30 Aug 2020 16:07:45

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-30T12:07:22', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '485a7abb-b139-45f2-a149-86637ee7cf27'	System	30 Aug 2020 16:07:45
User entered 'No (N)'	System	30 Aug 2020 16:07:45

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-30T12:07:42', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '485a7abb-b139-45f2-a149-86637ee7cf27'	System	30 Aug 2020 16:07:45
User entered '30 Aug 2020 12:07'	System	30 Aug 2020 16:07:45

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 17:12:37
User entered 'Day 4'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-31T17:03:25', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '6f35a39c-d2c3-46df-bfdc-01e8907c10aa'	System	31 Aug 2020 21:03:45
User entered 'Yes (Y)'	System	31 Aug 2020 21:03:45

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-31T17:03:32', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '6f35a39c-d2c3-46df-bfdc-01e8907c10aa'	System	31 Aug 2020 21:03:45
User entered '98.1'	System	31 Aug 2020 21:03:45

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-31T17:03:35', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '6f35a39c-d2c3-46df-bfdc-01e8907c10aa'	System	31 Aug 2020 21:03:45
User entered 'No (N)'	System	31 Aug 2020 21:03:45

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-31T17:03:43', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '6f35a39c-d2c3-46df-bfdc-01e8907c10aa'	System	31 Aug 2020 21:03:45
User entered '31 Aug 2020 17:03'	System	31 Aug 2020 21:03:45

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 17:12:37
User entered 'Day 5'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-01T17:53:16', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '8008ace5-e2fb-4b58-99cc-330c99e2c1cb'	System	01 Sep 2020 21:53:33
User entered 'Yes (Y)'	System	01 Sep 2020 21:53:33

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-01T17:53:23', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '8008ace5-e2fb-4b58-99cc-330c99e2c1cb' User entered '97.7'	System	01 Sep 2020 21:53:33
	System	01 Sep 2020 21:53:33

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-01T17:53:27', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '8008ace5-e2fb-4b58-99cc-330c99e2c1cb'	System	01 Sep 2020 21:53:33
User entered 'No (N)'	System	01 Sep 2020 21:53:33

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-01T17:53:31', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '8008ace5-e2fb-4b58-99cc-330c99e2c1cb'	System	01 Sep 2020 21:53:33
User entered '01 Sep 2020 17:53'	System	01 Sep 2020 21:53:33

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 17:12:37
User entered 'Day 6'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-02T12:56:46', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '373deb22-790b-4f72-b973-6cd6e674707b'	System	02 Sep 2020 16:57:03
User entered 'Yes (Y)'	System	02 Sep 2020 16:57:03

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-02T12:56:51', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '373deb22-790b-4f72-b973-6cd6e674707b' User entered '98.7'	System	02 Sep 2020 16:57:03
	System	02 Sep 2020 16:57:03

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-02T12:56:53', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '373deb22-790b-4f72-b973-6cd6e674707b'	System	02 Sep 2020 16:57:03
User entered 'No (N)'	System	02 Sep 2020 16:57:03

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-02T12:56:58', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '373deb22-790b-4f72-b973-6cd6e674707b'	System	02 Sep 2020 16:57:03
User entered '02 Sep 2020 12:56'	System	02 Sep 2020 16:57:03

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 17:12:37
User entered 'Day 7'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-03T12:35:28', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '0146f403-814e-4b73-b5f2-8ec0113a8357'	System	03 Sep 2020 16:35:52
User entered 'Yes (Y)'	System	03 Sep 2020 16:35:52

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-03T12:35:41', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '0146f403-814e-4b73-b5f2-8ec0113a8357'	System	03 Sep 2020 16:35:52
User entered '96.3'	System	03 Sep 2020 16:35:52

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-03T12:35:44', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '0146f403-814e-4b73-b5f2-8ec0113a8357'	System	03 Sep 2020 16:35:52
User entered 'No (N)'	System	03 Sep 2020 16:35:52

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-03T12:35:49', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '0146f403-814e-4b73-b5f2-8ec0113a8357'	System	03 Sep 2020 16:35:52
User entered '03 Sep 2020 12:35'	System	03 Sep 2020 16:35:52

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 17:12:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:08

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (382e5f362d67230c)', Time: '2020-08-28T13:40:33', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'f0675f77-5eb3-4d3b-b4a8-f84c5c9673f0'	System	28 Aug 2020 17:40:57
User entered 'None (1)'	System	28 Aug 2020 17:40:57

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (382e5f362d67230c)', Time: '2020-08-28T13:40:38', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'f0675f77-5eb3-4d3b-b4a8-f84c5c9673f0'	System	28 Aug 2020 17:40:57
User entered 'No (N)'	System	28 Aug 2020 17:40:57

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (382e5f362d67230c)', Time: '2020-08-28T13:40:42', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'f0675f77-5eb3-4d3b-b4a8-f84c5c9673f0'	System	28 Aug 2020 17:40:57
User entered 'No (N)'	System	28 Aug 2020 17:40:57

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:08

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (382e5f362d67230c)', Time: '2020-08-28T13:40:50', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'f0675f77-5eb3-4d3b-b4a8-f84c5c9673f0'	System	28 Aug 2020 17:40:57
User entered 'None (1)'	System	28 Aug 2020 17:40:57

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (382e5f362d67230c)', Time: '2020-08-28T13:40:55', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'f0675f77-5eb3-4d3b-b4a8-f84c5c9673f0'	System	28 Aug 2020 17:40:57
User entered '28 Aug 2020 13:40'	System	28 Aug 2020 17:40:57

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 13:28'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 15:58'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 17:12:37
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:08

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (382e5f362d67230c)', Time: '2020-08-28T18:28:31', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '032b92e4-477b-4b2a-9291-12887c7cdb95'	System	28 Aug 2020 22:29:22
User entered 'None (1)'	System	28 Aug 2020 22:29:22

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (382e5f362d67230c)', Time: '2020-08-28T18:28:52', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '032b92e4-477b-4b2a-9291-12887c7cdb95'	System	28 Aug 2020 22:29:22
User entered 'No (N)'	System	28 Aug 2020 22:29:22

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (382e5f362d67230c)', Time: '2020-08-28T18:28:57', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '032b92e4-477b-4b2a-9291-12887c7cdb95'	System	28 Aug 2020 22:29:22
User entered 'No (N)'	System	28 Aug 2020 22:29:22

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:08

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (382e5f362d67230c)', Time: '2020-08-28T18:29:09', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '032b92e4-477b-4b2a-9291-12887c7cdb95'	System	28 Aug 2020 22:29:22
User entered 'None (1)'	System	28 Aug 2020 22:29:22

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (382e5f362d67230c)', Time: '2020-08-28T18:29:19', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '032b92e4-477b-4b2a-9291-12887c7cdb95'	System	28 Aug 2020 22:29:22
User entered '28 Aug 2020 18:29'	System	28 Aug 2020 22:29:22

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 16:53'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 17:12:37
User entered 'Day 2'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:08

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-29T12:12:29', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '4de9384d-429b-4348-b462-1dceb2d2eddd'	System	29 Aug 2020 16:12:50
User entered 'None (1)'	System	29 Aug 2020 16:12:50

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-29T12:12:33', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '4de9384d-429b-4348-b462-1dceb2d22edd'	System	29 Aug 2020 16:12:50
User entered 'No (N)'	System	29 Aug 2020 16:12:50

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-29T12:12:37', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '4de9384d-429b-4348-b462-1dceb2d22edd'	System	29 Aug 2020 16:12:50
User entered 'No (N)'	System	29 Aug 2020 16:12:50

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:08

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-29T12:12:42', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '4de9384d-429b-4348-b462-1dceb2d22edd'	System	29 Aug 2020 16:12:50
User entered 'None (1)'	System	29 Aug 2020 16:12:50

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-29T12:12:49', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '4de9384d-429b-4348-b462-1dceb2d22edd'	System	29 Aug 2020 16:12:50
User entered '29 Aug 2020 12:12'	System	29 Aug 2020 16:12:50

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 17:12:37
User entered 'Day 3'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:08

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-30T12:07:51', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'ac31a55f-9072-4a66-8fff-531a7ca250ef'	System	30 Aug 2020 16:08:25
User entered 'None (1)'	System	30 Aug 2020 16:08:25

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-30T12:07:54', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'ac31a55f-9072-4a66-8fff-531a7ca250ef'	System	30 Aug 2020 16:08:25
User entered 'No (N)'	System	30 Aug 2020 16:08:25

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-30T12:08:02', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'ac31a55f-9072-4a66-8fff-531a7ca250ef'	System	30 Aug 2020 16:08:25
User entered 'No (N)'	System	30 Aug 2020 16:08:25

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:08

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-30T12:08:14', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'ac31a55f-9072-4a66-8fff-531a7ca250ef'	System	30 Aug 2020 16:08:25
User entered 'None (1)'	System	30 Aug 2020 16:08:25

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-30T12:08:22', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'ac31a55f-9072-4a66-8fff-531a7ca250ef' User entered '30 Aug 2020 12:08'	System	30 Aug 2020 16:08:25
	System	30 Aug 2020 16:08:25

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 17:12:37
User entered 'Day 4'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:08

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-31T17:03:50', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '19df79bd-b0eb-412a-b970-c6636f976402'	System	31 Aug 2020 21:04:20
User entered 'None (1)'	System	31 Aug 2020 21:04:20

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-31T17:03:53', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '19df79bd-b0eb-412a-b970-c6636f976402'	System	31 Aug 2020 21:04:20
User entered 'No (N)'	System	31 Aug 2020 21:04:20

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-31T17:03:57', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '19df79bd-b0eb-412a-b970-c6636f976402'	System	31 Aug 2020 21:04:20
User entered 'No (N)'	System	31 Aug 2020 21:04:20

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:08

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-31T17:04:07', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '19df79bd-b0eb-412a-b970-c6636f976402'	System	31 Aug 2020 21:04:20
User entered 'None (1)'	System	31 Aug 2020 21:04:20

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-31T17:04:18', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '19df79bd-b0eb-412a-b970-c6636f976402'	System	31 Aug 2020 21:04:20
User entered '31 Aug 2020 17:04'	System	31 Aug 2020 21:04:20

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 17:12:37
User entered 'Day 5'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:08

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-01T17:53:36', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '6b6d4b03-14f5-429d-b543-7fd983da12e7'	System	01 Sep 2020 21:53:56
User entered 'None (1)'	System	01 Sep 2020 21:53:56

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-01T17:53:40', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '6b6d4b03-14f5-429d-b543-7fd983da12e7'	System	01 Sep 2020 21:53:56
User entered 'No (N)'	System	01 Sep 2020 21:53:56

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-01T17:53:43', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '6b6d4b03-14f5-429d-b543-7fd983da12e7'	System	01 Sep 2020 21:53:56
User entered 'No (N)'	System	01 Sep 2020 21:53:56

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:08

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-01T17:53:51', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '6b6d4b03-14f5-429d-b543-7fd983da12e7'	System	01 Sep 2020 21:53:56
User entered 'None (1)'	System	01 Sep 2020 21:53:56

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-01T17:53:55', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '6b6d4b03-14f5-429d-b543-7fd983da12e7'	System	01 Sep 2020 21:53:56
User entered '01 Sep 2020 17:53'	System	01 Sep 2020 21:53:56

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 17:12:37
User entered 'Day 6'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:08

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-02T12:57:05', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '3bada313-0e1e-4c9f-bbf0-798aacc4b156'	System	02 Sep 2020 16:57:26
User entered 'None (1)'	System	02 Sep 2020 16:57:26

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-02T12:57:08', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '3bada313-0e1e-4c9f-bbf0-798aacc4b156'	System	02 Sep 2020 16:57:26
User entered 'No (N)'	System	02 Sep 2020 16:57:26

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-02T12:57:14', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '3bada313-0e1e-4c9f-bbf0-798aacc4b156'	System	02 Sep 2020 16:57:26
User entered 'No (N)'	System	02 Sep 2020 16:57:26

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:08

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-02T12:57:20', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '3bada313-0e1e-4c9f-bbf0-798aacc4b156'	System	02 Sep 2020 16:57:26
User entered 'None (1)'	System	02 Sep 2020 16:57:26

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-02T12:57:24', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '3bada313-0e1e-4c9f-bbf0-798aacc4b156'	System	02 Sep 2020 16:57:26
User entered '02 Sep 2020 12:57'	System	02 Sep 2020 16:57:26

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 17:12:37
User entered 'Day 7'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:08

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-03T12:35:59', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '56c52984-5ad8-4057-8016-e8fb3dc469ab'	System	03 Sep 2020 16:36:08
User entered 'None (1)'	System	03 Sep 2020 16:36:08

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-03T12:35:57', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '56c52984-5ad8-4057-8016-e8fb3dc469ab'	System	03 Sep 2020 16:36:08
User entered 'No (N)'	System	03 Sep 2020 16:36:08

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-03T12:36:01', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '56c52984-5ad8-4057-8016-e8fb3dc469ab'	System	03 Sep 2020 16:36:08
User entered 'No (N)'	System	03 Sep 2020 16:36:08

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:08

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-03T12:36:03', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '56c52984-5ad8-4057-8016-e8fb3dc469ab'	System	03 Sep 2020 16:36:08
User entered 'None (1)'	System	03 Sep 2020 16:36:08

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-03T12:36:06', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '56c52984-5ad8-4057-8016-e8fb3dc469ab' User entered '03 Sep 2020 12:36'	System	03 Sep 2020 16:36:08
	System	03 Sep 2020 16:36:08

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 17:12:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (382e5f362d67230c)', Time: '2020-08-28T13:41:02', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'dc50d056-4d6c-44ff-b619-e3d3c21d42fa'	System	28 Aug 2020 17:41:36
User entered 'None (0)'	System	28 Aug 2020 17:41:36

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (382e5f362d67230c)', Time: '2020-08-28T13:41:09', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'dc50d056-4d6c-44ff-b619-e3d3c21d42fa'	System	28 Aug 2020 17:41:36
User entered 'None (0)'	System	28 Aug 2020 17:41:36

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (382e5f362d67230c)', Time: '2020-08-28T13:41:13', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'dc50d056-4d6c-44ff-b619-e3d3c21d42fa'	System	28 Aug 2020 17:41:36
User entered 'None (0)'	System	28 Aug 2020 17:41:36

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (382e5f362d67230c)', Time: '2020-08-28T13:41:17', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'dc50d056-4d6c-44ff-b619-e3d3c21d42fa'	System	28 Aug 2020 17:41:36
User entered 'None (0)'	System	28 Aug 2020 17:41:36

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (382e5f362d67230c)', Time: '2020-08-28T13:41:20', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'dc50d056-4d6c-44ff-b619-e3d3c21d42fa'	System	28 Aug 2020 17:41:36
User entered 'None (0)'	System	28 Aug 2020 17:41:36

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (382e5f362d67230c)', Time: '2020-08-28T13:41:23', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'dc50d056-4d6c-44ff-b619-e3d3c21d42fa'	System	28 Aug 2020 17:41:36
User entered 'None (0)'	System	28 Aug 2020 17:41:36

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (382e5f362d67230c)', Time: '2020-08-28T13:41:27', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'dc50d056-4d6c-44ff-b619-e3d3c21d42fa'	System	28 Aug 2020 17:41:36
User entered 'No (N)'	System	28 Aug 2020 17:41:36

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (382e5f362d67230c)', Time: '2020-08-28T13:41:30', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'dc50d056-4d6c-44ff-b619-e3d3c21d42fa'	System	28 Aug 2020 17:41:36
User entered '28 Aug 2020 13:41'	System	28 Aug 2020 17:41:36

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 13:28'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 15:58'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 17:12:37
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (382e5f362d67230c)', Time: '2020-08-28T18:29:31', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'edfa6896-7172-4d08-9afc-8a22e7b98436'	System	28 Aug 2020 22:30:23
User entered 'No interference with activity (1)'	System	28 Aug 2020 22:30:23

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (382e5f362d67230c)', Time: '2020-08-28T18:29:38', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'edfa6896-7172-4d08-9afc-8a22e7b98436'	System	28 Aug 2020 22:30:23
User entered 'None (0)'	System	28 Aug 2020 22:30:23

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (382e5f362d67230c)', Time: '2020-08-28T18:29:42', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'edfa6896-7172-4d08-9afc-8a22e7b98436'	System	28 Aug 2020 22:30:23
User entered 'None (0)'	System	28 Aug 2020 22:30:23

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (382e5f362d67230c)', Time: '2020-08-28T18:29:51', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'edfa6896-7172-4d08-9afc-8a22e7b98436'	System	28 Aug 2020 22:30:23
User entered 'None (0)'	System	28 Aug 2020 22:30:23

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (382e5f362d67230c)', Time: '2020-08-28T18:29:55', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'edfa6896-7172-4d08-9afc-8a22e7b98436'	System	28 Aug 2020 22:30:23
User entered 'None (0)'	System	28 Aug 2020 22:30:23

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (382e5f362d67230c)', Time: '2020-08-28T18:29:58', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'edfa6896-7172-4d08-9afc-8a22e7b98436'	System	28 Aug 2020 22:30:23
User entered 'None (0)'	System	28 Aug 2020 22:30:23

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (382e5f362d67230c)', Time: '2020-08-28T18:30:12', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'edfa6896-7172-4d08-9afc-8a22e7b98436'	System	28 Aug 2020 22:30:23
User entered 'No (N)'	System	28 Aug 2020 22:30:23

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (382e5f362d67230c)', Time: '2020-08-28T18:30:18', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'edfa6896-7172-4d08-9afc-8a22e7b98436'	System	28 Aug 2020 22:30:23
User entered '28 Aug 2020 18:30'	System	28 Aug 2020 22:30:23

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 16:53'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 17:12:37
User entered 'Day 2'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-29T12:13:07', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '83d97584-3de3-4b6b-9790-9298bbe562f7'	System	29 Aug 2020 16:13:54
User entered 'No interference with activity (1)'	System	29 Aug 2020 16:13:54

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-29T12:13:28', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '83d97584-3de3-4b6b-9790-9298bbe562f7'	System	29 Aug 2020 16:13:54
User entered 'No interference with activity (1)'	System	29 Aug 2020 16:13:54

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-29T12:13:22', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '83d97584-3de3-4b6b-9790-9298bbe562f7'	System	29 Aug 2020 16:13:54
User entered 'None (0)'	System	29 Aug 2020 16:13:54

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-29T12:13:21', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '83d97584-3de3-4b6b-9790-9298bbe562f7'	System	29 Aug 2020 16:13:54
User entered 'None (0)'	System	29 Aug 2020 16:13:54

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-29T12:13:31', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '83d97584-3de3-4b6b-9790-9298bbe562f7'	System	29 Aug 2020 16:13:54
User entered 'None (0)'	System	29 Aug 2020 16:13:54

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-29T12:13:33', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '83d97584-3de3-4b6b-9790-9298bbe562f7'	System	29 Aug 2020 16:13:54
User entered 'None (0)'	System	29 Aug 2020 16:13:54

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-29T12:13:39', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '83d97584-3de3-4b6b-9790-9298bbe562f7'	System	29 Aug 2020 16:13:54
User entered 'No (N)'	System	29 Aug 2020 16:13:54

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-29T12:13:51', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '83d97584-3de3-4b6b-9790-9298bbe562f7'	System	29 Aug 2020 16:13:54
User entered '29 Aug 2020 12:13'	System	29 Aug 2020 16:13:54

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 17:12:37
User entered 'Day 3'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-30T12:08:31', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '44a7da62-37dd-458c-88b9-d6f581366112'	System	30 Aug 2020 16:08:55
User entered 'None (0)'	System	30 Aug 2020 16:08:55

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-30T12:08:35', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '44a7da62-37dd-458c-88b9-d6f581366112'	System	30 Aug 2020 16:08:55
User entered 'None (0)'	System	30 Aug 2020 16:08:55

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-30T12:08:37', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '44a7da62-37dd-458c-88b9-d6f581366112'	System	30 Aug 2020 16:08:55
User entered 'None (0)'	System	30 Aug 2020 16:08:55

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-30T12:08:39', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '44a7da62-37dd-458c-88b9-d6f581366112'	System	30 Aug 2020 16:08:55
User entered 'None (0)'	System	30 Aug 2020 16:08:55

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-30T12:08:42', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '44a7da62-37dd-458c-88b9-d6f581366112'	System	30 Aug 2020 16:08:55
User entered 'None (0)'	System	30 Aug 2020 16:08:55

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-30T12:08:44', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '44a7da62-37dd-458c-88b9-d6f581366112'	System	30 Aug 2020 16:08:55
User entered 'None (0)'	System	30 Aug 2020 16:08:55

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-30T12:08:48', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '44a7da62-37dd-458c-88b9-d6f581366112'	System	30 Aug 2020 16:08:55
User entered 'No (N)'	System	30 Aug 2020 16:08:55

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-30T12:08:53', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '44a7da62-37dd-458c-88b9-d6f581366112'	System	30 Aug 2020 16:08:55
User entered '30 Aug 2020 12:08'	System	30 Aug 2020 16:08:55

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 17:12:37
User entered 'Day 4'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-31T17:04:27', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'd27e75af-7654-4602-8c3a-8f0e962a52bf'	System	31 Aug 2020 21:05:04
User entered 'None (0)'	System	31 Aug 2020 21:05:04

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-31T17:04:29', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'd27e75af-7654-4602-8c3a-8f0e962a52bf'	System	31 Aug 2020 21:05:04
User entered 'No interference with activity (1)'	System	31 Aug 2020 21:05:04

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-31T17:04:38', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'd27e75af-7654-4602-8c3a-8f0e962a52bf'	System	31 Aug 2020 21:05:04
User entered 'None (0)'	System	31 Aug 2020 21:05:04

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-31T17:04:47', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'd27e75af-7654-4602-8c3a-8f0e962a52bf'	System	31 Aug 2020 21:05:04
User entered 'None (0)'	System	31 Aug 2020 21:05:04

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-31T17:04:49', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'd27e75af-7654-4602-8c3a-8f0e962a52bf'	System	31 Aug 2020 21:05:04
User entered 'None (0)'	System	31 Aug 2020 21:05:04

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-31T17:04:51', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'd27e75af-7654-4602-8c3a-8f0e962a52bf'	System	31 Aug 2020 21:05:04
User entered 'None (0)'	System	31 Aug 2020 21:05:04

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-31T17:04:57', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'd27e75af-7654-4602-8c3a-8f0e962a52bf'	System	31 Aug 2020 21:05:04
User entered 'No (N)'	System	31 Aug 2020 21:05:04

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-08-31T17:05:02', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'd27e75af-7654-4602-8c3a-8f0e962a52bf'	System	31 Aug 2020 21:05:04
User entered '31 Aug 2020 17:05'	System	31 Aug 2020 21:05:04

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 17:12:37
User entered 'Day 5'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-01T17:54:02', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'fb9d7230-a077-4d0b-9176-1afbe99fbd71'	System	01 Sep 2020 21:54:27
User entered 'None (0)'	System	01 Sep 2020 21:54:27

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-01T17:54:06', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'fb9d7230-a077-4d0b-9176-1afbe99fbd71'	System	01 Sep 2020 21:54:27
User entered 'No interference with activity (1)'	System	01 Sep 2020 21:54:27

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-01T17:54:09', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'fb9d7230-a077-4d0b-9176-1afbe99fbd71'	System	01 Sep 2020 21:54:27
User entered 'None (0)'	System	01 Sep 2020 21:54:27

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-01T17:54:11', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'fb9d7230-a077-4d0b-9176-1afbe99fbd71'	System	01 Sep 2020 21:54:27
User entered 'None (0)'	System	01 Sep 2020 21:54:27

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-01T17:54:14', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'fb9d7230-a077-4d0b-9176-1afbe99fbd71'	System	01 Sep 2020 21:54:27
User entered 'None (0)'	System	01 Sep 2020 21:54:27

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-01T17:54:16', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'fb9d7230-a077-4d0b-9176-1afbe99fbd71'	System	01 Sep 2020 21:54:27
User entered 'None (0)'	System	01 Sep 2020 21:54:27

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-01T17:54:19', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'fb9d7230-a077-4d0b-9176-1afbe99fbd71'	System	01 Sep 2020 21:54:27
User entered 'No (N)'	System	01 Sep 2020 21:54:27

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-01T17:54:25', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'fb9d7230-a077-4d0b-9176-1afbe99fbd71'	System	01 Sep 2020 21:54:27
User entered '01 Sep 2020 17:54'	System	01 Sep 2020 21:54:27

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 17:12:37
User entered 'Day 6'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-02T12:57:28', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'a17c8445-14d1-45f8-9b36-0997518711a4'	System	02 Sep 2020 16:57:48
User entered 'None (0)'	System	02 Sep 2020 16:57:48

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-02T12:57:30', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'a17c8445-14d1-45f8-9b36-0997518711a4'	System	02 Sep 2020 16:57:48
User entered 'None (0)'	System	02 Sep 2020 16:57:48

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-02T12:57:33', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'a17c8445-14d1-45f8-9b36-0997518711a4'	System	02 Sep 2020 16:57:48
User entered 'None (0)'	System	02 Sep 2020 16:57:48

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-02T12:57:35', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'a17c8445-14d1-45f8-9b36-0997518711a4'	System	02 Sep 2020 16:57:48
User entered 'None (0)'	System	02 Sep 2020 16:57:48

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-02T12:57:36', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'a17c8445-14d1-45f8-9b36-0997518711a4'	System	02 Sep 2020 16:57:48
User entered 'None (0)'	System	02 Sep 2020 16:57:48

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-02T12:57:39', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'a17c8445-14d1-45f8-9b36-0997518711a4'	System	02 Sep 2020 16:57:48
User entered 'None (0)'	System	02 Sep 2020 16:57:48

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-02T12:57:41', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'a17c8445-14d1-45f8-9b36-0997518711a4'	System	02 Sep 2020 16:57:48
User entered 'No (N)'	System	02 Sep 2020 16:57:48

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-02T12:57:45', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'a17c8445-14d1-45f8-9b36-0997518711a4'	System	02 Sep 2020 16:57:48
User entered '02 Sep 2020 12:57'	System	02 Sep 2020 16:57:48

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 17:12:37
User entered 'Day 7'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-03T12:36:16', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '181cc879-7234-426f-84f1-2240f779f29a'	System	03 Sep 2020 16:36:50
User entered 'No interference with activity (1)'	System	03 Sep 2020 16:36:50

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-03T12:36:20', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '181cc879-7234-426f-84f1-2240f779f29a'	System	03 Sep 2020 16:36:50
User entered 'No interference with activity (1)'	System	03 Sep 2020 16:36:50

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-03T12:36:23', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '181cc879-7234-426f-84f1-2240f779f29a'	System	03 Sep 2020 16:36:50
User entered 'No interference with activity (1)'	System	03 Sep 2020 16:36:50

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-03T12:36:27', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '181cc879-7234-426f-84f1-2240f779f29a'	System	03 Sep 2020 16:36:50
User entered 'No interference with activity (1)'	System	03 Sep 2020 16:36:50

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-03T12:36:30', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '181cc879-7234-426f-84f1-2240f779f29a'	System	03 Sep 2020 16:36:50
User entered 'None (0)'	System	03 Sep 2020 16:36:50

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-03T12:36:32', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '181cc879-7234-426f-84f1-2240f779f29a'	System	03 Sep 2020 16:36:50
User entered 'None (0)'	System	03 Sep 2020 16:36:50

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-03T12:36:37', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '181cc879-7234-426f-84f1-2240f779f29a'	System	03 Sep 2020 16:36:50
User entered 'No (N)'	System	03 Sep 2020 16:36:50

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-03T12:36:48', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '181cc879-7234-426f-84f1-2240f779f29a'	System	03 Sep 2020 16:36:50
User entered '03 Sep 2020 12:36'	System	03 Sep 2020 16:36:50

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 17:12:37

US3542090

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 16:36:50
User entered 'Day 8'	System	03 Sep 2020 16:36:50

US3542090

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:36:08

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-04T15:46:41', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'b8df66b2-4bf7-46c9-9ec0-1be6838cd81a'	System	04 Sep 2020 19:46:53
User entered 'None (0)'	System	04 Sep 2020 19:46:53

US3542090

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:36:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-04T15:46:50', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'b8df66b2-4bf7-46c9-9ec0-1be6838cd81a'	System	04 Sep 2020 19:46:53
User entered '04 Sep 2020 15:46'	System	04 Sep 2020 19:46:53

US3542090

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 16:36:50

US3542090

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 16:36:50

US3542090

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 16:36:50
User entered 'Day 8'	System	03 Sep 2020 16:36:50

US3542090

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:36:08

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-04T15:46:58', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '9d9d7f20-9333-439e-8c4c-8c8b5a0841c0'	System	04 Sep 2020 19:47:05
User entered 'None (0)'	System	04 Sep 2020 19:47:05

US3542090

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:36:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-04T15:47:01', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '9d9d7f20-9333-439e-8c4c-8c8b5a0841c0'	System	04 Sep 2020 19:47:05
User entered '04 Sep 2020 15:47'	System	04 Sep 2020 19:47:05

US3542090

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 16:36:50

US3542090

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 16:36:50

US3542090

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 16:36:50
User entered 'Day 8'	System	03 Sep 2020 16:36:50

US3542090

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:36:08

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-04T15:47:07', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '4d88f962-a0f2-44f3-bace-e8428fdfebde'	System	04 Sep 2020 19:47:12
User entered 'No interference with activity (1)'	System	04 Sep 2020 19:47:12

US3542090

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:36:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-04T15:47:10', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '4d88f962-a0f2-44f3-bace-e8428fdfebde'	System	04 Sep 2020 19:47:12
User entered '04 Sep 2020 15:47'	System	04 Sep 2020 19:47:12

US3542090

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 16:36:50

US3542090

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 16:36:50

US3542090

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 16:36:50
User entered 'Day 9'	System	03 Sep 2020 16:36:50

US3542090

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:36:08

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-05T12:45:34', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'e216fa37-670a-44b0-992b-20ed6ee775dd'	System	05 Sep 2020 16:45:39
User entered 'None (0)'	System	05 Sep 2020 16:45:39

US3542090

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:36:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-05T12:45:38', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'e216fa37-670a-44b0-992b-20ed6ee775dd'	System	05 Sep 2020 16:45:39
User entered '05 Sep 2020 12:45'	System	05 Sep 2020 16:45:39

US3542090

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 16:36:50

US3542090

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 16:36:50

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 16:36:50
User entered 'Day 8'	System	03 Sep 2020 16:36:50

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:36:08

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-04T15:47:16', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '70148247-b4e2-44ed-81a9-eb661030bc84'	System	04 Sep 2020 19:47:21
User entered 'No interference with activity (1)'	System	04 Sep 2020 19:47:21

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:36:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-04T15:47:19', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '70148247-b4e2-44ed-81a9-eb661030bc84'	System	04 Sep 2020 19:47:21
User entered '04 Sep 2020 15:47'	System	04 Sep 2020 19:47:21

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 16:36:50

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 16:36:50

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 16:36:50
User entered 'Day 9'	System	03 Sep 2020 16:36:50

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:36:08

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-05T12:45:43', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '2a83708c-1f40-45c4-bd7f-f7c24275ed28'	System	05 Sep 2020 16:45:49
User entered 'No interference with activity (1)'	System	05 Sep 2020 16:45:49

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:36:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-05T12:45:47', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '2a83708c-1f40-45c4-bd7f-f7c24275ed28'	System	05 Sep 2020 16:45:49
User entered '05 Sep 2020 12:45'	System	05 Sep 2020 16:45:49

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 16:36:50

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 16:36:50

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 19:47:21
User entered 'Day 10'	System	04 Sep 2020 19:47:21

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:36:08

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-06T12:01:24', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'c385f650-c938-49a5-ae4b-d04026f78815'	System	06 Sep 2020 16:02:14
User entered 'No interference with activity (1)'	System	06 Sep 2020 16:02:14

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:36:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-06T12:01:28', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'c385f650-c938-49a5-ae4b-d04026f78815'	System	06 Sep 2020 16:02:14
User entered '06 Sep 2020 12:01'	System	06 Sep 2020 16:02:14

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 19:47:21

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 19:47:21

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Sep 2020 16:45:49
User entered 'Day 11'	System	05 Sep 2020 16:45:49

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:36:08

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-08T05:59:49', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'e2f5693b-0b8e-4615-8ddf-2cffb7777148'	System	08 Sep 2020 09:59:58
User entered 'No interference with activity (1)'	System	08 Sep 2020 09:59:58

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:36:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-08T05:59:56', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'e2f5693b-0b8e-4615-8ddf-2cffb7777148'	System	08 Sep 2020 09:59:58
User entered '08 Sep 2020 05:59'	System	08 Sep 2020 09:59:58

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 16:45:49

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 16:45:49

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Sep 2020 16:02:14
User entered 'Day 12'	System	06 Sep 2020 16:02:14

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:36:08

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-08T12:03:58', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '4b223178-85a0-4ddd-98fc-a445b5458368'	System	08 Sep 2020 16:04:20
User entered 'No interference with activity (1)'	System	08 Sep 2020 16:04:20

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:36:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-08T12:04:02', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '4b223178-85a0-4ddd-98fc-a445b5458368'	System	08 Sep 2020 16:04:20
User entered '08 Sep 2020 12:04'	System	08 Sep 2020 16:04:20

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	06 Sep 2020 16:02:14

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	06 Sep 2020 16:02:14

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 09:59:58
User entered 'Day 13'	System	08 Sep 2020 09:59:58

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 09:36:08

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-09T13:07:42', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '4c2ec5c3-a034-4da2-98cb-e44781a89780'	System	09 Sep 2020 17:07:55
User entered 'No interference with activity (1)'	System	09 Sep 2020 17:07:55

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 09:36:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-09T13:07:52', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '4c2ec5c3-a034-4da2-98cb-e44781a89780'	System	09 Sep 2020 17:07:55
User entered '09 Sep 2020 13:07'	System	09 Sep 2020 17:07:55

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 09:59:58

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 09:59:58

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 16:04:20
User entered 'Day 14'	System	08 Sep 2020 16:04:20

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 09:36:08

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-10T12:00:29', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '1a2f812b-706c-4864-801b-f4b7983a4ad6'	System	10 Sep 2020 16:00:43
User entered 'None (0)'	System	10 Sep 2020 16:00:43

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 09:36:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-10T12:00:32', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '1a2f812b-706c-4864-801b-f4b7983a4ad6'	System	10 Sep 2020 16:00:43
User entered '10 Sep 2020 12:00'	System	10 Sep 2020 16:00:43

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 16:04:20

US3542090

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 16:04:20

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 16:36:50
User entered 'Day 8'	System	03 Sep 2020 16:36:50

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-04T15:47:26', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'ac7cd741-7f39-41f9-a164-28c379067406'	System	04 Sep 2020 19:47:31
User entered 'No (N)'	System	04 Sep 2020 19:47:31

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:36:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-04T15:47:29', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'ac7cd741-7f39-41f9-a164-28c379067406'	System	04 Sep 2020 19:47:31
User entered '04 Sep 2020 15:47'	System	04 Sep 2020 19:47:31

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 16:36:50

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 16:36:50

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 16:36:50
User entered 'Day 9'	System	03 Sep 2020 16:36:50

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-05T12:45:50', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '35865ab0-2457-447f-bd2d-1135c56c40f0'	System	05 Sep 2020 16:45:57
User entered 'No (N)'	System	05 Sep 2020 16:45:57

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:36:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-05T12:45:55', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '35865ab0-2457-447f-bd2d-1135c56c40f0'	System	05 Sep 2020 16:45:57
User entered '05 Sep 2020 12:45'	System	05 Sep 2020 16:45:57

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 16:36:50

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 16:36:50

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Sep 2020 16:45:49
DataPoint Inactivated.	System	05 Sep 2020 16:45:39
Data entry locked.	System	04 Sep 2020 19:47:12
User entered 'Day 10'	System	04 Sep 2020 19:47:12

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-06T12:01:32', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'a8083cb9-3cfc-485d-a0e7-35d1dff89ca1'	System	06 Sep 2020 16:02:23
User entered 'No (N)'	System	06 Sep 2020 16:02:23
DataPoint Activated.	System	05 Sep 2020 16:45:49
DataPoint Inactivated.	System	05 Sep 2020 16:45:39

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:36:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-06T12:01:36', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'a8083cb9-3cfc-485d-a0e7-35d1dff89ca1'	System	06 Sep 2020 16:02:23
User entered '06 Sep 2020 12:01'	System	06 Sep 2020 16:02:23
DataPoint Activated.	System	05 Sep 2020 16:45:49
DataPoint Inactivated.	System	05 Sep 2020 16:45:39

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Sep 2020 16:45:49
DataPoint Inactivated.	System	05 Sep 2020 16:45:39
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 19:47:12

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Sep 2020 16:45:49
DataPoint Inactivated.	System	05 Sep 2020 16:45:39
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 19:47:12

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Sep 2020 16:45:49
User entered 'Day 11'	System	05 Sep 2020 16:45:49

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-08T06:00:06', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '5fd6d47d-028b-4152-b7fe-65cf2ab2c65a'	System	08 Sep 2020 10:00:12
User entered 'No (N)'	System	08 Sep 2020 10:00:12

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:36:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-08T06:00:10', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '5fd6d47d-028b-4152-b7fe-65cf2ab2c65a'	System	08 Sep 2020 10:00:12
User entered '08 Sep 2020 06:00'	System	08 Sep 2020 10:00:12

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 16:45:49

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 16:45:49

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Sep 2020 16:02:14
User entered 'Day 12'	System	06 Sep 2020 16:02:14

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-08T12:04:06', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '5b874423-627e-4bbd-a9f9-519cdcc06df9'	System	08 Sep 2020 16:04:24
User entered 'No (N)'	System	08 Sep 2020 16:04:24

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:36:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-08T12:04:10', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '5b874423-627e-4bbd-a9f9-519cdcc06df9'	System	08 Sep 2020 16:04:24
User entered '08 Sep 2020 12:04'	System	08 Sep 2020 16:04:24

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	06 Sep 2020 16:02:14

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	06 Sep 2020 16:02:14

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 09:59:58
User entered 'Day 13'	System	08 Sep 2020 09:59:58

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-09T13:07:55', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '44cb0e01-4215-4f6c-97db-0a68b0f91b96'	System	09 Sep 2020 17:08:04
User entered 'No (N)'	System	09 Sep 2020 17:08:04

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:36:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-09T13:08:02', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '44cb0e01-4215-4f6c-97db-0a68b0f91b96'	System	09 Sep 2020 17:08:04
User entered '09 Sep 2020 13:08'	System	09 Sep 2020 17:08:04

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 09:59:58

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 09:59:58

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 16:04:20
User entered 'Day 14'	System	08 Sep 2020 16:04:20

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-10T12:00:35', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'b78b56d7-a7c2-44f2-adf2-58808f66d9d7'	System	10 Sep 2020 16:00:54
User entered 'No (N)'	System	10 Sep 2020 16:00:54

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:36:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-09-10T12:00:40', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'b78b56d7-a7c2-44f2-adf2-58808f66d9d7'	System	10 Sep 2020 16:00:54
User entered '10 Sep 2020 12:00'	System	10 Sep 2020 16:00:54

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:36:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 16:04:20

US3542090

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:36:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 16:04:20

US3542090

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:57:48
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:45:22
	(b) (4)	
User entered 'Yes (Y)'	Madhu Balachandran	08 Sep 2020 18:02:33
	(b) (4)	

US3542090

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:08

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:57:48
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:45:22
	(b) (4)	
User entered '4 Sep 2020'	Madhu Balachandran	08 Sep 2020 18:02:33
	(b) (4)	

US3542090

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:57:48
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:45:22
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Madhu Balachandran	08 Sep 2020 18:02:33
	(b) (4)	

US3542090

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:57:48
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:45:22
	(b) (4)	
User entered empty.	Madhu Balachandran	08 Sep 2020 18:02:33
	(b) (4)	

US3542090

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:45:22
	(b) (4)	
User entered 'Yes (Y)'	Madhu Balachandran	08 Sep 2020 18:02:24
	(b) (4)	

US3542090

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 18:02:24

US3542090

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:29:38
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
	(b) (4)	
User entered 'Yes (Y)'	Madhu Balachandran	14 Sep 2020 17:57:50
	(b) (4)	

US3542090

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:08

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:29:38
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
	(b) (4)	
User entered '11 Sep 2020'	Madhu Balachandran	14 Sep 2020 17:57:50
	(b) (4)	

US3542090

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:29:38
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Madhu Balachandran	14 Sep 2020 17:57:50
	(b) (4)	

US3542090

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:29:38
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
	(b) (4)	
User entered empty.	Madhu Balachandran	14 Sep 2020 17:57:50
	(b) (4)	

US3542090

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
	(b) (4)	
User entered 'Yes (Y)'	Madhu Balachandran	14 Sep 2020 17:57:52
	(b) (4)	

US3542090

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 17:57:52

US3542090

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 19:39:29
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:14:39
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	22 Sep 2020 16:41:46

US3542090

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 19:39:29
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:14:39
User entered '18 Sep 2020'	(b) (4) Madhu Balachandran (b) (4)	22 Sep 2020 16:41:46

US3542090

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 19:39:29
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:14:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Madhu Balachandran (b) (4)	22 Sep 2020 16:41:46

US3542090

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 19:39:29
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:14:39
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	22 Sep 2020 16:41:46

US3542090

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 19:39:45
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:14:39
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	22 Sep 2020 16:41:28

US3542090

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 16:41:28

US3542090

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:36:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
	(b) (4)	
User entered 'Yes (Y)'	DeEnna Wedding (b) (4)	19 Oct 2020 18:45:06
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:36:08

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	21 Oct 2020 07:00:20
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'dose discontinuation' (Site from System).	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 19:37:27
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	19 Oct 2020 18:45:06
User entered '10 Oct 2020'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:45:06

US3542090

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
	(b) (4)	
User entered 'Clinic (Clinic)'	DeEnna Wedding (b) (4)	19 Oct 2020 18:45:06
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:36:08

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	19 Oct 2020 18:45:06

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:08

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	DeEnna Wedding (b) (4)	19 Oct 2020 18:46:24

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
	(b) (4)	
User entered 'Yes (Y)'	DeEnna Wedding (b) (4)	19 Oct 2020 18:46:24
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
	(b) (4)	
User entered '10 Oct 2020'	DeEnna Wedding (b) (4)	19 Oct 2020 18:46:24
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
	(b) (4)	
User entered '13:02'	DeEnna Wedding (b) (4)	19 Oct 2020 18:46:24
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered '10 Oct 2020 13:02'	System	19 Oct 2020 18:46:24

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:08

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
	(b) (4)	
User entered '98.2' F	DeEnna Wedding (b) (4)	19 Oct 2020 18:46:24
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:08

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
	(b) (4)	
User entered 'Oral (Oral)'	DeEnna Wedding (b) (4)	19 Oct 2020 18:46:24
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:08

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
	(b) (4)	
User entered empty.	DeEnna Wedding (b) (4)	19 Oct 2020 18:46:24
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
	(b) (4)	
User entered '79'	DeEnna Wedding (b) (4)	19 Oct 2020 18:46:24
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:08

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Oct 2020 18:46:24

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
	(b) (4)	
User entered '16'	DeEnna Wedding (b) (4)	19 Oct 2020 18:46:24
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Oct 2020 18:46:24

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
	(b) (4)	
User entered '136'	DeEnna Wedding (b) (4)	19 Oct 2020 18:46:24
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Oct 2020 18:46:24

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
	(b) (4)	
User entered '78'	DeEnna Wedding (b) (4)	19 Oct 2020 18:46:24
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Oct 2020 18:46:24

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:08

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:46:24

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 18:46:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Oct 2020 18:46:30
User entered 'No (N)' reason for change: Data Entry Error	DeEnna Wedding (b) (4)	19 Oct 2020 18:46:30
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 18:46:24
User entered empty.	DeEnna Wedding (b) (4)	19 Oct 2020 18:46:24
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
	(b) (4)	
User entered empty.	DeEnna Wedding (b) (4)	19 Oct 2020 18:46:24
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
	(b) (4)	
User entered empty.	DeEnna Wedding (b) (4)	19 Oct 2020 18:46:24
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:46:24

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:08

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
	(b) (4)	
User entered empty.	DeEnna Wedding (b) (4)	19 Oct 2020 18:46:24
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:08

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
	(b) (4)	
User entered empty.	DeEnna Wedding (b) (4)	19 Oct 2020 18:46:24
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:08

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
	(b) (4)	
User entered empty.	DeEnna Wedding (b) (4)	19 Oct 2020 18:46:24
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
	(b) (4)	
User entered empty.	DeEnna Wedding (b) (4)	19 Oct 2020 18:46:24
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:08

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:46:24

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
	(b) (4)	
User entered empty.	DeEnna Wedding (b) (4)	19 Oct 2020 18:46:24
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:46:24

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
	(b) (4)	
User entered empty.	DeEnna Wedding (b) (4)	19 Oct 2020 18:46:24
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:46:24

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
	(b) (4)	
User entered empty.	DeEnna Wedding (b) (4)	19 Oct 2020 18:46:24
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:46:24

US3542090

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
	(b) (4)	
User entered 'Yes (Y)'	DeEnna Wedding (b) (4)	19 Oct 2020 18:46:40
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
	(b) (4)	
User entered '10 Oct 2020'	DeEnna Wedding (b) (4)	19 Oct 2020 18:46:40
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:36:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 04:00:06
	(b) (4)	
User entered 'No (N)'	David Diemert (b) (4)	10 Oct 2020 17:49:02
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:36:08

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 04:00:06
User entered 'Participant declined due to Adverse Event (ADVERSE EVENT)'	David Diemert (b) (4)	10 Oct 2020 17:49:02

US3542090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 04:00:06
	(b) (4)	
User entered empty.	David Diemert (b) (4)	10 Oct 2020 17:49:02
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:36:08

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Oct 2020 17:49:02

US3542090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:36:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	14 Oct 2020 04:00:06
User entered empty.	David Diemert (b) (4) (b) (4)	10 Oct 2020 17:49:02

US3542090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 04:00:06
	(b) (4)	
User entered empty.	David Diemert (b) (4)	10 Oct 2020 17:49:02
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered empty.	System	10 Oct 2020 17:49:02

US3542090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 04:00:06
	(b) (4)	
User entered empty.	David Diemert (b) (4)	10 Oct 2020 17:49:02
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered empty.	System	10 Oct 2020 17:49:02

US3542090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered empty.	System	10 Oct 2020 17:49:02

US3542090

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
	(b) (4)	
User entered 'Yes (Y)'	DeEnna Wedding (b) (4)	19 Oct 2020 18:46:57
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
	(b) (4)	
User entered '10 Oct 2020'	DeEnna Wedding (b) (4)	19 Oct 2020 18:46:57
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:08

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
	(b) (4)	
User entered '13:13'	DeEnna Wedding (b) (4)	19 Oct 2020 18:46:57
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered '10 Oct 2020 13:13'	System	19 Oct 2020 18:46:57

US3542090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:36:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
	(b) (4)	
User entered '10 Oct 2020'	DeEnna Wedding (b) (4)	19 Oct 2020 18:47:19
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:36:08

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	DeEnna Wedding (b) (4)	19 Oct 2020 18:47:19

US3542090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:36:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
	(b) (4)	
User entered 'Yes (Y)'	DeEnna Wedding (b) (4)	19 Oct 2020 18:47:19
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:36:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
	(b) (4)	
User entered '13:15'	DeEnna Wedding (b) (4)	19 Oct 2020 18:47:19
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered '10 Oct 2020 13:15'	System	19 Oct 2020 18:47:19

US3542090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:36:08

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	DeEnna Wedding (b) (4)	19 Oct 2020 18:47:19

US3542090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:36:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
	(b) (4)	
User entered 'No (N)'	DeEnna Wedding (b) (4)	19 Oct 2020 18:47:19
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:36:08

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
	(b) (4)	
User entered empty.	DeEnna Wedding (b) (4)	19 Oct 2020 18:47:19
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:47:19

US3542090

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
	(b) (4)	
User entered 'Yes (Y)'	DeEnna Wedding (b) (4)	19 Oct 2020 18:47:26
	(b) (4)	

US3542090

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 18:47:26

US3542090

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	04 Nov 2020 18:40:51
	(b) (4)	

US3542090

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 18:40:51

US3542090

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	04 Nov 2020 18:40:56
	(b) (4)	

US3542090

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 18:40:56

US3542090

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	04 Nov 2020 18:41:02
	(b) (4)	

US3542090

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 18:41:02

US3542090

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:36:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	04 Nov 2020 18:41:16
	(b) (4)	

US3542090

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered '3 Nov 2020'	Erika Faust (b) (4)	04 Nov 2020 18:41:16
	(b) (4)	

US3542090

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
User entered 'Clinic (Clinic)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 18:41:16

US3542090

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:36:08

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	04 Nov 2020 18:41:16

US3542090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:14
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	04 Nov 2020 18:41:45
	(b) (4)	

US3542090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:14
User closed query 'Per CDM: Per CCG, Date should be recorded in (dd MMM yyyy) format. Please review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:13:23
Query 'Per CDM: Per CCG, Date should be recorded in (dd MMM yyyy) format. Please review and update accordingly. ' answered with 'Date updated' (Site from DM).	Erika Faust (b) (4) (b) (4)	13 Nov 2020 14:13:20
User entered '03 Nov 2020' reason for change: Per Query Resolution	Erika Faust (b) (4) (b) (4)	13 Nov 2020 14:13:12
User opened query 'Per CDM: Per CCG, Date should be recorded in (dd MMM yyyy) format. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 11:54:56
User entered '3 Nov 2020'	Erika Faust (b) (4) (b) (4)	04 Nov 2020 18:41:45

US3542090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:14
	(b) (4)	
User entered '12:42'	Erika Faust (b) (4)	04 Nov 2020 18:41:45
	(b) (4)	

US3542090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered '03 Nov 2020 12:42'	System	13 Nov 2020 14:13:12
User entered '3 Nov 2020 12:42'	System	04 Nov 2020 18:41:45

US3542090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:14
	(b) (4)	
User entered '98.4' F	Erika Faust (b) (4)	04 Nov 2020 18:41:45
	(b) (4)	

US3542090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:14
	(b) (4)	
User entered 'Oral (Oral)'	Erika Faust (b) (4)	04 Nov 2020 18:41:45
	(b) (4)	

US3542090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:14
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	04 Nov 2020 18:41:45
	(b) (4)	

US3542090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:14
	(b) (4)	
User entered '76'	Erika Faust (b) (4)	04 Nov 2020 18:41:45
	(b) (4)	

US3542090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	04 Nov 2020 18:41:45

US3542090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:14
	(b) (4)	
User entered '12'	Erika Faust (b) (4)	04 Nov 2020 18:41:45
	(b) (4)	

US3542090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	04 Nov 2020 18:41:45

US3542090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:14
	(b) (4)	
User entered '135'	Erika Faust (b) (4)	04 Nov 2020 18:41:45
	(b) (4)	

US3542090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Nov 2020 18:41:45

US3542090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:14
	(b) (4)	
User entered '83'	Erika Faust (b) (4)	04 Nov 2020 18:41:45
	(b) (4)	

US3542090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Nov 2020 18:41:45

US3542090

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	04 Nov 2020 18:41:53
	(b) (4)	

US3542090

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered '3 Nov 2020'	Erika Faust (b) (4)	04 Nov 2020 18:41:53
	(b) (4)	

US3542090

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered 'No (N)'	Erika Faust (b) (4)	04 Nov 2020 18:41:59
	(b) (4)	

US3542090

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	04 Nov 2020 18:41:59
	(b) (4)	

US3542090

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	04 Nov 2020 18:41:59
	(b) (4)	

US3542090

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 18:41:59

US3542090

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	04 Nov 2020 18:42:09
	(b) (4)	

US3542090

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 18:42:09

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 17:12:37
User entered 'Day 64'	System	28 Aug 2020 17:12:37

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[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 (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-11-01T19:37:16', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '1d5f0cc8-f324-4548-8362-2183c1e91922'	System	02 Nov 2020 00:38:46
User entered 'Yes (Y)'	System	02 Nov 2020 00:38:46

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

Have you been exposed to someone with 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 (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-11-01T19:37:21', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '1d5f0cc8-f324-4548-8362-2183c1e91922'	System	02 Nov 2020 00:38:46
User entered 'No (N)'	System	02 Nov 2020 00:38:46

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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 (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-11-01T19:37:31', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '1d5f0cc8-f324-4548-8362-2183c1e91922'	System	02 Nov 2020 00:38:46
User entered 'Yes (Y)'	System	02 Nov 2020 00:38:46

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-11-01T19:37:52', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '1d5f0cc8-f324-4548-8362-2183c1e91922'	System	02 Nov 2020 00:38:46
User entered '0'	System	02 Nov 2020 00:38:46

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-11-01T19:37:52', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '1d5f0cc8-f324-4548-8362-2183c1e91922'	System	02 Nov 2020 00:38:46
User entered '0'	System	02 Nov 2020 00:38:46

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-11-01T19:37:52', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '1d5f0cc8-f324-4548-8362-2183c1e91922'	System	02 Nov 2020 00:38:46
User entered '0'	System	02 Nov 2020 00:38:46

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-11-01T19:37:52', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '1d5f0cc8-f324-4548-8362-2183c1e91922'	System	02 Nov 2020 00:38:46
User entered '0'	System	02 Nov 2020 00:38:46

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-11-01T19:37:52', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '1d5f0cc8-f324-4548-8362-2183c1e91922'	System	02 Nov 2020 00:38:46
User entered '0'	System	02 Nov 2020 00:38:46

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-11-01T19:37:52', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '1d5f0cc8-f324-4548-8362-2183c1e91922'	System	02 Nov 2020 00:38:46
User entered '1'	System	02 Nov 2020 00:38:46

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-11-01T19:37:52', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '1d5f0cc8-f324-4548-8362-2183c1e91922'	System	02 Nov 2020 00:38:46
User entered '1'	System	02 Nov 2020 00:38:46

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-11-01T19:37:52', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '1d5f0cc8-f324-4548-8362-2183c1e91922'	System	02 Nov 2020 00:38:46
User entered '1'	System	02 Nov 2020 00:38:46

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-11-01T19:37:52', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '1d5f0cc8-f324-4548-8362-2183c1e91922'	System	02 Nov 2020 00:38:46
User entered '1'	System	02 Nov 2020 00:38:46

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-11-01T19:37:52', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '1d5f0cc8-f324-4548-8362-2183c1e91922'	System	02 Nov 2020 00:38:46
User entered '0'	System	02 Nov 2020 00:38:46

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-11-01T19:37:52', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '1d5f0cc8-f324-4548-8362-2183c1e91922'	System	02 Nov 2020 00:38:46
User entered '0'	System	02 Nov 2020 00:38:46

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-11-01T19:37:52', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '1d5f0cc8-f324-4548-8362-2183c1e91922'	System	02 Nov 2020 00:38:46
User entered '1'	System	02 Nov 2020 00:38:46

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-11-01T19:37:52', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '1d5f0cc8-f324-4548-8362-2183c1e91922'	System	02 Nov 2020 00:38:46
User entered '1'	System	02 Nov 2020 00:38:46

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-11-01T19:37:52', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '1d5f0cc8-f324-4548-8362-2183c1e91922'	System	02 Nov 2020 00:38:46
User entered '1'	System	02 Nov 2020 00:38:46

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-11-01T19:37:52', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '1d5f0cc8-f324-4548-8362-2183c1e91922'	System	02 Nov 2020 00:38:46
User entered '0'	System	02 Nov 2020 00:38:46

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-11-01T19:37:52', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '1d5f0cc8-f324-4548-8362-2183c1e91922'	System	02 Nov 2020 00:38:46
User entered '0'	System	02 Nov 2020 00:38:46

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-11-01T19:37:52', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '1d5f0cc8-f324-4548-8362-2183c1e91922'	System	02 Nov 2020 00:38:46
User entered '0'	System	02 Nov 2020 00:38:46

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Please 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 (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-11-01T19:38:00', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '1d5f0cc8-f324-4548-8362-2183c1e91922'	System	02 Nov 2020 00:38:46
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Nov 2020 00:38:46

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[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 (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-11-01T19:38:08', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '1d5f0cc8-f324-4548-8362-2183c1e91922'	System	02 Nov 2020 00:38:46
User entered 'Yes (Y)'	System	02 Nov 2020 00:38:46

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Please 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 (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-11-01T19:38:14', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '1d5f0cc8-f324-4548-8362-2183c1e91922'	System	02 Nov 2020 00:38:46
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Nov 2020 00:38:46

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-11-01T19:38:26', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '1d5f0cc8-f324-4548-8362-2183c1e91922'	System	02 Nov 2020 00:38:46
User entered '01 Nov 2020 19:38:26'	System	02 Nov 2020 00:38:46

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 17:12:37
User entered '28 Oct 2020 00:01'	System	28 Aug 2020 17:12:37

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 17:12:37
User entered '01 Nov 2020 23:59'	System	28 Aug 2020 17:12:37

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 17:12:37
User entered 'Day 71'	System	28 Aug 2020 17:12:37

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[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 (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-11-04T15:13:02', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '6374b49c-77b7-40bd-89b2-e69a82bf2f41'	System	04 Nov 2020 20:13:25
User entered 'No (N)'	System	04 Nov 2020 20:13:25

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

Have you been exposed to someone with 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 (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-11-04T15:13:11', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '6374b49c-77b7-40bd-89b2-e69a82bf2f41'	System	04 Nov 2020 20:13:25
User entered 'No (N)'	System	04 Nov 2020 20:13:25

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-11-04T15:13:20', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '6374b49c-77b7-40bd-89b2-e69a82bf2f41'	System	04 Nov 2020 20:13:25
User entered '04 Nov 2020 15:13:20'	System	04 Nov 2020 20:13:25

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 17:12:37
User entered '04 Nov 2020 00:01'	System	28 Aug 2020 17:12:37

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 17:12:37
User entered '08 Nov 2020 23:59'	System	28 Aug 2020 17:12:37

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '25 Oct 2020 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '29 Oct 2020 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '01 Nov 2020 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '05 Nov 2020 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '08 Nov 2020 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '12 Nov 2020 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '15 Nov 2020 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '19 Nov 2020 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 19:47:26

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 19:47:26

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '23 Oct 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '27 Oct 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '30 Oct 2022 00:01'	System	19 Nov 2020 19:47:26

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:47:26
Amendment Manager: User entered '03 Nov 2022 23:59'	System	19 Nov 2020 19:47:26

US3542090

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:36:08

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
	(b) (4)	
User entered 'Yes (Y)'	Madhu Balachandran	14 Sep 2020 17:58:32
	(b) (4)	

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Soft tissue disorders NEC, PT: Groin pain, LLT: Groin pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Sep 2020 11:28:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 11:28:40
Data point term sent to Coder	System	14 Sep 2020 17:59:48
User entered 'Right Groin Pain'	Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
	(b) (4)	
User entered 'No (N)'	Madhu Balachandran	14 Sep 2020 17:59:17
	(b) (4)	

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
	(b) (4)	
User entered 'No (N)'	Madhu Balachandran	14 Sep 2020 17:59:17
	(b) (4)	

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
	(b) (4)	
User entered '4 Sep 2020'	Madhu Balachandran	14 Sep 2020 17:59:17
	(b) (4)	

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
	(b) (4)	
User entered empty.	Madhu Balachandran	14 Sep 2020 17:59:17
	(b) (4)	

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 17:59:17

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
	(b) (4)	
User entered 'No (N)'	Madhu Balachandran	14 Sep 2020 17:59:17
	(b) (4)	

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
	(b) (4)	
User entered '4 Sep 2020'	Madhu Balachandran	14 Sep 2020 17:59:17
	(b) (4)	

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
	(b) (4)	
User entered empty.	Madhu Balachandran	14 Sep 2020 17:59:17
	(b) (4)	

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 17:59:17

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
	(b) (4)	
User entered 'No (N)'	Madhu Balachandran	14 Sep 2020 17:59:17
	(b) (4)	

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
	(b) (4)	
User entered '0'	Madhu Balachandran	14 Sep 2020 17:59:17
	(b) (4)	

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
	(b) (4)	
User entered '0'	Madhu Balachandran	14 Sep 2020 17:59:17
	(b) (4)	

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
	(b) (4)	
User entered empty.	Madhu Balachandran	14 Sep 2020 17:59:17
	(b) (4)	

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
	(b) (4)	
User entered empty.	Madhu Balachandran	14 Sep 2020 17:59:17
	(b) (4)	

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
	(b) (4)	
User entered empty.	Madhu Balachandran	14 Sep 2020 17:59:17
	(b) (4)	

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
	(b) (4)	
User entered '0'	Madhu Balachandran	14 Sep 2020 17:59:17
	(b) (4)	

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
User entered 'Not Related (NOT RELATED)'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
User entered 'Not Related (NOT RELATED)'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 17:59:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 17:59:55
User entered 'None (NONE)' reason for change: Data Entry Error	Madhu Balachandran (b) (4)	14 Sep 2020 17:59:55
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 17:59:17
User entered empty.	Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
	(b) (4)	
User entered '1'	Madhu Balachandran	14 Sep 2020 17:59:17
	(b) (4)	

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
	(b) (4)	
User entered '0'	Madhu Balachandran	14 Sep 2020 17:59:17
	(b) (4)	

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
	(b) (4)	
User entered '0'	Madhu Balachandran	14 Sep 2020 17:59:17
	(b) (4)	

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
	(b) (4)	
User entered empty.	Madhu Balachandran	14 Sep 2020 17:59:17
	(b) (4)	

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	14 Sep 2020 17:59:17

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Sep 2020 17:59:17

US3542090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Polyarthralgia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 16:40:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 16:40:37
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:22:10
Data point term sent to Coder	System	03 Nov 2020 21:06:25
Coding entries removed.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:05:41
User entered 'Polyarthralgias' reason for change: New Information	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:05:41
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 18:51:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 18:51:25
Data point term sent to Coder	System	19 Oct 2020 18:50:27
User entered 'knee pain, bilateral'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:49:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:22:10
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 21:05:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 21:05:41
User entered 'Yes (Y)' reason for change: New Information	David Diemert (b) (4)	03 Nov 2020 21:05:41
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 18:49:35
User entered empty.	DeEnna Wedding (b) (4)	19 Oct 2020 18:49:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this AE refers to JOINT ACHES IN SEVERAL JOINTS. If yes, this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4)	06 Nov 2020 05:56:51
	David Diemert (b) (4)	03 Nov 2020 21:22:10
Query 'Per DM CLR: Please review if this AE refers to JOINT ACHES IN SEVERAL JOINTS. If yes, this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification.' answered with 'Updated.' (Site from DM).	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:11:57
User entered 'Yes (Y)' reason for change: Per Query Resolution	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:11:48
User opened query 'Per DM CLR: Please review if this AE refers to JOINT ACHES IN SEVERAL JOINTS. If yes, this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification.' (Site from DM). User entered 'No (N)'	(b) (4), (b) (6) DeEnna Wedding (b) (4) (b) (4)	02 Nov 2020 11:27:47 19 Oct 2020 18:49:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:22:10
	(b) (4)	
User entered 'No (N)'	DeEnna Wedding (b) (4)	19 Oct 2020 18:49:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom JOINT ACHES IN SEVERAL JOINTS on 03 SEP 2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	06 Nov 2020 05:59:04
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom JOINT ACHES IN SEVERAL JOINTS on 03 SEP 2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'Updated.' (Site from DM).	David Diemert (b) (4)	03 Nov 2020 21:22:10
User entered '03 Sep 2020' reason for change: Data Entry Error	David Diemert (b) (4)	03 Nov 2020 21:13:09
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom JOINT ACHES IN SEVERAL JOINTS on 03 SEP 2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	David Diemert (b) (4)	03 Nov 2020 21:13:03
User entered '04 Sep 2020'	DeEnna Wedding (b) (4)	19 Oct 2020 18:49:35

US3542090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:22:10
	(b) (4)	
User entered empty.	DeEnna Wedding (b) (4)	19 Oct 2020 18:49:35
	(b) (4)	

US3542090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:49:35

US3542090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:22:10
	(b) (4)	
User entered 'Yes (Y)'	DeEnna Wedding (b) (4)	19 Oct 2020 18:49:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:22:10
	(b) (4)	
User entered empty.	DeEnna Wedding (b) (4)	19 Oct 2020 18:49:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:22:10
	(b) (4)	
User entered empty.	DeEnna Wedding (b) (4)	19 Oct 2020 18:49:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:49:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
Signature has been broken.	Erika Faust (b) (4)	04 Nov 2020 18:49:20
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Erika Faust (b) (4)	04 Nov 2020 18:49:20
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:22:10
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	DeEnna Wedding (b) (4)	19 Oct 2020 18:49:35
	(b) (4)	

US3542090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:22:10
	(b) (4)	
User entered 'No (N)'	DeEnna Wedding (b) (4)	19 Oct 2020 18:49:35
	(b) (4)	

US3542090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:22:10
	(b) (4)	
User entered '0'	DeEnna Wedding (b) (4)	19 Oct 2020 18:49:35
	(b) (4)	

US3542090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:22:10
	(b) (4)	
User entered '0'	DeEnna Wedding (b) (4)	19 Oct 2020 18:49:35
	(b) (4)	

US3542090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:22:10
	(b) (4)	
User entered '0'	DeEnna Wedding (b) (4)	19 Oct 2020 18:49:35
	(b) (4)	

US3542090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:22:10
	(b) (4)	
User entered empty.	DeEnna Wedding (b) (4)	19 Oct 2020 18:49:35
	(b) (4)	

US3542090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:22:10
	(b) (4)	
User entered empty.	DeEnna Wedding (b) (4)	19 Oct 2020 18:49:35
	(b) (4)	

US3542090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:22:10
	(b) (4)	
User entered empty.	DeEnna Wedding (b) (4)	19 Oct 2020 18:49:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:22:10
	(b) (4)	
User entered empty.	DeEnna Wedding (b) (4)	19 Oct 2020 18:49:35
	(b) (4)	

US3542090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:22:10
	(b) (4)	
User entered '0'	DeEnna Wedding (b) (4)	19 Oct 2020 18:49:35
	(b) (4)	

US3542090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:22:10
	(b) (4)	
User entered '0'	DeEnna Wedding (b) (4)	19 Oct 2020 18:49:35
	(b) (4)	

US3542090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:22:10
	(b) (4)	
User entered '0'	DeEnna Wedding (b) (4)	19 Oct 2020 18:49:35
	(b) (4)	

US3542090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:22:10
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	DeEnna Wedding (b) (4)	19 Oct 2020 18:49:35
	(b) (4)	

US3542090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:22:10
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	DeEnna Wedding (b) (4)	19 Oct 2020 18:49:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:22:10
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4) DeEnna Wedding (b) (4)	19 Oct 2020 18:49:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:22:10
	(b) (4)	
User entered '1'	DeEnna Wedding (b) (4)	19 Oct 2020 18:49:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:22:10
	(b) (4)	
User entered '0'	DeEnna Wedding (b) (4)	19 Oct 2020 18:49:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:22:10
	(b) (4)	
User entered '0'	DeEnna Wedding (b) (4)	19 Oct 2020 18:49:35
	(b) (4)	

US3542090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:22:10
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) DeEnna Wedding (b) (4)	19 Oct 2020 18:49:35

US3542090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:22:10
	(b) (4)	
User entered empty.	DeEnna Wedding (b) (4)	19 Oct 2020 18:49:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:22:10
	(b) (4)	
User entered empty.	DeEnna Wedding (b) (4)	19 Oct 2020 18:49:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	19 Oct 2020 18:49:35

US3542090

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 21:05:41

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:36:08

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:34:41

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:08

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 21:15:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 21:15:25
Data point term sent to Coder	System	03 Nov 2020 21:14:34
Coding entries removed.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:14:11
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 23:40:46
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 Sep 2020 23:40:46
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 03:07:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 03:07:52
Data point term sent to Coder	System	31 Aug 2020 18:36:09
User entered 'Vitamin D'	Madhu Balachandran (b) (4)	31 Aug 2020 18:35:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 07:39:14
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
Query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify.' answered with 'Updated to yes' (Site from DM).	Hannah Yellin (b) (4)	11 Nov 2020 17:07:01
Signature has been broken.	Hannah Yellin (b) (4)	11 Nov 2020 17:06:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Hannah Yellin (b) (4)	11 Nov 2020 17:06:46
User opened query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:14:29
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'No (N)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:35:52

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:08

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 05:20:27
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:22:10
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'Corrected.' (Site from DM).	David Diemert (b) (4)	03 Nov 2020 21:14:18
Signature has been broken.	David Diemert (b) (4)	03 Nov 2020 21:14:11
User entered 'General health prophylaxis' reason for change: Per Query Resolution	David Diemert (b) (4)	03 Nov 2020 21:14:11
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 10:29:39
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'Over the Counter'	Madhu Balachandran (b) (4)	31 Aug 2020 18:35:52

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'UNK'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:35:52

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'Other (OTHER)'	Madhu Balachandran	31 Aug 2020 18:35:52
	(b) (4)	

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:08

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'Unknown'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:35:52

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'once daily (QD)'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:35:52

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:35:52

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'Oral (ORAL)'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:35:52

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:35:52

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'UN Aug 2019'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:35:52

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:35:52

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:35:52

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:35:52

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:35:52

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 18:35:52

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 18:35:52

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 18:35:52

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:08

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 21:16:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 21:16:29
Data point term sent to Coder	System	03 Nov 2020 21:15:36
Coding entries removed.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:14:57
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 03:07:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 03:07:53
Data point term sent to Coder	System	31 Aug 2020 18:37:10
User entered 'Vitamin C'	Madhu Balachandran (b) (4)	31 Aug 2020 18:36:44

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 07:39:28
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
Query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify.'	Hannah Yellin (b) (4)	11 Nov 2020 17:07:17
answered with 'Updated to yes' (Site from DM). Signature has been broken.	Hannah Yellin (b) (4)	11 Nov 2020 17:07:10
User entered 'Yes (Y)' reason for change: New Information	Hannah Yellin (b) (4)	11 Nov 2020 17:07:10
User opened query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:14:59
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'No (N)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:36:44

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:08

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 05:25:58
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:22:10
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'Updated.' (Site from DM).	David Diemert (b) (4)	03 Nov 2020 21:15:02
Signature has been broken.	David Diemert (b) (4)	03 Nov 2020 21:14:57
User entered 'General health prophylaxis' reason for change: Per Query Resolution	David Diemert (b) (4)	03 Nov 2020 21:14:57
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 10:29:50
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'Over the counter (immune system)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:36:44

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'UNK'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:36:44

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'Other (OTHER)'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:36:44

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:08

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'Unknown'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:36:44

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'once daily (QD)'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:36:44

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:36:44

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'Oral (ORAL)'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:36:44

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:36:44

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'UN Aug 2019'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:36:44

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:36:44

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:36:44

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:36:44

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:36:44

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 18:36:44

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 18:36:44

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 18:36:44

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:08

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 21:16:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 21:16:30
Data point term sent to Coder	System	03 Nov 2020 21:15:37
Coding entries removed.	David Diemert (b) (4)	03 Nov 2020 21:15:31
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 18:39:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 18:39:35
Data point term sent to Coder	System	31 Aug 2020 18:38:11
User entered 'Fish Oil'	Madhu Balachandran (b) (4)	31 Aug 2020 18:37:17

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 07:39:35
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
Query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify.'	Hannah Yellin (b) (4)	11 Nov 2020 17:07:32
answered with 'Updated to yes' (Site from DM). Signature has been broken.	Hannah Yellin (b) (4)	11 Nov 2020 17:07:25
User entered 'Yes (Y)' reason for change: New Information	Hannah Yellin (b) (4)	11 Nov 2020 17:07:25
User opened query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:15:19
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'No (N)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:37:17

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:08

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 05:26:03
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:22:10
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'Updated.' (Site from DM).	David Diemert (b) (4)	03 Nov 2020 21:15:36
Signature has been broken.	David Diemert (b) (4)	03 Nov 2020 21:15:31
User entered 'General health prophylaxis' reason for change: New Information	David Diemert (b) (4)	03 Nov 2020 21:15:31
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 10:30:14
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'Cholesterol'	Madhu Balachandran (b) (4)	31 Aug 2020 18:37:17

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'UNK'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:37:17

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'Other (OTHER)'	Madhu Balachandran	31 Aug 2020 18:37:17
	(b) (4)	

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:08

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'Unknown'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:37:17

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'once daily (QD)'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:37:17

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:37:17

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'Oral (ORAL)'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:37:17

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:37:17

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'UN Aug 2019'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:37:17

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:37:17

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:37:17

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:37:17

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:37:17

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 18:37:17

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 18:37:17

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 18:37:17

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:08

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: ALLIUM SATIVUM, PRODUCTSYNONYM: GARLIC [ALLIUM SATIVUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 16:52:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 16:52:25
Data point term sent to Coder Coding entries removed.	System David Diemert (b) (4) (b) (4)	03 Nov 2020 21:16:37 03 Nov 2020 21:15:47
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: TONICS, ATC: TONICS, ATC: HERBAL TONICS, OTHER, PRODUCT: ALLIUM SATIVUM, PRODUCTSYNONYM: GARLIC [ALLIUM SATIVUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 05:21:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 05:21:39
Data point term sent to Coder User entered 'Garlic Pills'	System Madhu Balachandran (b) (4)	31 Aug 2020 18:38:11 31 Aug 2020 18:37:48

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 07:40:16
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
Query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify.'	(b) (4)	
answered with 'Updated to yes' (Site from DM).	Hannah Yellin (b) (4)	11 Nov 2020 17:07:47
Signature has been broken.	(b) (4)	
	Hannah Yellin (b) (4)	11 Nov 2020 17:07:40
User entered 'Yes (Y)' reason for change: New Information	(b) (4)	
	Hannah Yellin (b) (4)	11 Nov 2020 17:07:40
User opened query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:15:52
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'No (N)'	Madhu Balachandran	31 Aug 2020 18:37:48
	(b) (4)	

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:08

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 05:26:08
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:22:10
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'Updted.' (Site from DM).	David Diemert (b) (4)	03 Nov 2020 21:15:52
Signature has been broken.	David Diemert (b) (4)	03 Nov 2020 21:15:47
User entered 'General health prophylaxis' reason for change: New Information	David Diemert (b) (4)	03 Nov 2020 21:15:47
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 10:30:21
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'Over the counter (immune system)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:37:48

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'UNK'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:37:48

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'Other (OTHER)'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:37:48

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'Unknown'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:37:48

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'once daily (QD)'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:37:48

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:37:48

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'Oral (ORAL)'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:37:48

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:37:48

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'UN Aug 2019'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:37:48

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:37:48

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:37:48

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:37:48

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:37:48

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 18:37:48

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 18:37:48

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 18:37:48

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:08

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 21:19:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 21:19:41
Data point term sent to Coder Coding entries removed.	System David Diemert (b) (4) (b) (4)	03 Nov 2020 21:18:41 03 Nov 2020 21:18:32
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 10:20:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 10:20:02
Data point term sent to Coder User entered 'Multivitamin'	System Madhu Balachandran (b) (4)	31 Aug 2020 18:39:12 31 Aug 2020 18:38:26

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:38:26

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 21:22:10
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	03 Nov 2020 21:18:32
	(b) (4)	
User entered 'General health prophylaxis' reason for change: New Information	David Diemert (b) (4)	03 Nov 2020 21:18:32
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'Over the counter - General Health'	Madhu Balachandran	31 Aug 2020 18:38:26
	(b) (4)	

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'UNK'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:38:26

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'Other (OTHER)'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:38:26

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'Unknown'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:38:26

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'once daily (QD)'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:38:26

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:38:26

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'Oral (ORAL)'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:38:26

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:38:26

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
	(b) (4)	
User entered 'UN Aug 2019' reason for change:	Hannah Yellin (b) (4)	04 Sep 2020 18:50:40
Data Entry Error	(b) (4)	
User entered 'UN UNK 2019'	Madhu Balachandran	31 Aug 2020 18:38:26
	(b) (4)	

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:38:26

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:38:26

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:38:26

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:38:26

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 18:38:26

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 18:38:26

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 18:38:26

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS USED IN ERECTILE DYSFUNCTION, PRODUCT: SILDENAFIL, PRODUCTSYNONYM: VIAGRA [SILDENAFIL] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	31 Aug 2020 18:40:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 18:40:34
Data point term sent to Coder	System	31 Aug 2020 18:39:14
User entered 'Viagra'	Madhu Balachandran (b) (4)	31 Aug 2020 18:39:07

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:39:07

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:08

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 03:58:07
Query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF. ' answered with 'Added to MH eCRF.' (Site from DM).	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:18:08
User opened query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 08:35:15
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 08:35:07
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 08:35:04
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'Erectile Dysfunction'	Madhu Balachandran (b) (4)	31 Aug 2020 18:39:07

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered '100'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:39:07

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'mg (mg)'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:39:07

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:08

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:39:07

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'as needed (PRN)'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:39:07

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:39:07

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'Oral (ORAL)'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:39:07

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:39:07

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'UN Jul 2012'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:39:07

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:39:07

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:39:07

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:39:07

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	31 Aug 2020 18:39:07

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 18:39:07

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 18:39:07

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 18:39:07

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Nov 2020 20:09:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 20:09:27
Data point term sent to Coder	System	04 Nov 2020 18:47:29
User entered 'Cyclobenzaprine'	Erika Faust (b) (4) (b) (4)	04 Nov 2020 18:46:51

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered 'No (N)'	Erika Faust (b) (4)	04 Nov 2020 18:46:51
	(b) (4)	

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
User entered 'Polyarthralgias'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 18:46:51

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered '5'	Erika Faust (b) (4)	04 Nov 2020 18:46:51
	(b) (4)	

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered 'mg (mg)'	Erika Faust (b) (4)	04 Nov 2020 18:46:51
	(b) (4)	

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	04 Nov 2020 18:46:51
	(b) (4)	

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered 'as needed (PRN)'	Erika Faust (b) (4)	04 Nov 2020 18:46:51
	(b) (4)	

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	04 Nov 2020 18:46:51
	(b) (4)	

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered 'Oral (ORAL)'	Erika Faust (b) (4)	04 Nov 2020 18:46:51
	(b) (4)	

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	04 Nov 2020 18:46:51
	(b) (4)	

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered '13 Oct 2020'	Erika Faust (b) (4)	04 Nov 2020 18:46:51
	(b) (4)	

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	04 Nov 2020 18:46:51
	(b) (4)	

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	04 Nov 2020 18:46:51
	(b) (4)	

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	04 Nov 2020 18:46:51
	(b) (4)	

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered 'No (N)'	Erika Faust (b) (4)	04 Nov 2020 18:46:51
	(b) (4)	

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 18:46:51

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 18:46:51

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 18:46:51

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
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: NAPROXEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Nov 2020 05:05:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 05:05:41
Data point term sent to Coder	System	04 Nov 2020 18:48:30
User entered 'Naproxen'	Erika Faust (b) (4) (b) (4)	04 Nov 2020 18:47:31

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered 'No (N)'	Erika Faust (b) (4)	04 Nov 2020 18:47:31
	(b) (4)	

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered 'Polyarthralgias'	Erika Faust (b) (4)	04 Nov 2020 18:47:31
	(b) (4)	

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered '500'	Erika Faust (b) (4)	04 Nov 2020 18:47:31
	(b) (4)	

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered 'mg (mg)'	Erika Faust (b) (4)	04 Nov 2020 18:47:31
	(b) (4)	

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:08

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	04 Nov 2020 18:47:31
	(b) (4)	

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered 'as needed (PRN)'	Erika Faust (b) (4)	04 Nov 2020 18:47:31
	(b) (4)	

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	04 Nov 2020 18:47:31
	(b) (4)	

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered 'Oral (ORAL)'	Erika Faust (b) (4)	04 Nov 2020 18:47:31
	(b) (4)	

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	04 Nov 2020 18:47:31
	(b) (4)	

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered '13 Oct 2020'	Erika Faust (b) (4)	04 Nov 2020 18:47:31
	(b) (4)	

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered '0'	Erika Faust (b) (4)	04 Nov 2020 18:47:31
	(b) (4)	

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	04 Nov 2020 18:47:31
	(b) (4)	

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	04 Nov 2020 18:47:31
	(b) (4)	

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:48:53
	(b) (4)	
User entered 'No (N)'	Erika Faust (b) (4)	04 Nov 2020 18:47:31
	(b) (4)	

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 18:47:31

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 18:47:31

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 18:47:31

US3542090

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:36:08

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
	(b) (4)	
User entered '10 Oct 2020'	DeEnna Wedding (b) (4)	19 Oct 2020 19:36:53
	(b) (4)	

US3542090

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:36:08

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
User entered 'AE (specify) (ADVERSE EVENT)'	(b) (4) DeEnna Wedding (b) (4)	19 Oct 2020 19:36:53

US3542090

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:36:08

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Nov 2020 16:51:57
User closed query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' (Site from DM).	(b) (4)	20 Nov 2020 05:54:59
Query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' answered with 'AE record number entered' (Site from DM).	Hannah Yellin (b) (4)	18 Nov 2020 16:43:59
Signature has been broken.	Hannah Yellin (b) (4)	18 Nov 2020 16:43:49
User entered 'AE #2' reason for change: Per Query Resolution	Hannah Yellin (b) (4)	18 Nov 2020 16:43:49
User opened query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:06:44
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:37:38
User entered 'patient attributes bilateral knee and elbow pain after dose 1 to IP and declines dose 2. Agrees to continue follow-up for safety.'	DeEnna Wedding (b) (4)	19 Oct 2020 19:36:53