US3542090 (Prod: George Washington University)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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

US3542090

Folder: Screening

Form: Demographics

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

Generated On: 11 Aug 2021 22:49:01

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

US3542090

Folder: Screening

Form: Enrollment

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

Generated On: 11 Aug 2021 22:49:01

Date of Informed Consent *(dd MMM yyyy)*	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

US3542090

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

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

Generated On: 11 Aug 2021 22:49:01

Did the participant meet all eligibility criteria?   Yes ⬤

No ◯

Were any significant conditions reported?   Yes ⬤

No ◯

Folder: Screening

Form: Medical History (1)

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

Generated On: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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

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Folder: Screening

Form: Medical History (4)

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

Generated On: 11 Aug 2021 22:49:01

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

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

Generated On: 11 Aug 2021 22:49:01

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
Height *(xxx.x)*	69 in
Weight *(xxx.x)*	187.8 lb
BMI *(xxx.x)*	27.79120 kg/m^2
BMI units	KG/M2
Temperature *(xxx.x)*	ND - Not Done
Route of measurement	Oral ○
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	ND - Not Done
Pulse units	BPM
Respiratory Rate *(xxx)*	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) **18 Dec 2020 16:16:13**

Generated On: 11 Aug 2021 22:49:01

| 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: Screening

Form: Risk of Exposure

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

Generated On: 11 Aug 2021 22:49:01

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**

Generated On: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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) **18 Dec 2020 16:16:13**

Generated On: 11 Aug 2021 22:49:01

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.

Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **05 Sep 2020 21:33:29**
Generated On: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

Is the participant continuing to the next visit?   Yes ●

                                                                    No ◯

Continuing Flag   1

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

FDA-CBER-2022-1614-2665501

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

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

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

FDA-CBER-2022-1614-2665504

US3542090
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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

FDA-CBER-2022-1614-2665506

US3542090
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:49:01

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

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

FDA-CBER-2022-1614-2665508

US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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

TIMEPOINT	DAY 2

Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○

Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○

PC Time Stamp	29 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: 11 Aug 2021 22:49:01

TIMEPOINT	DAY 3
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	30 AUG 2020 12:08
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

TIMEPOINT	DAY 4
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	31 AUG 2020 17:04
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

TIMEPOINT	DAY 5
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	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: 11 Aug 2021 22:49:01

TIMEPOINT	DAY 6
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	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: 11 Aug 2021 22:49:01

TIMEPOINT	DAY 7
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	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: 11 Aug 2021 22:49:01

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 ◯

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: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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 ●

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: 11 Aug 2021 22:49:01

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 ●

	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

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 ⬤

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: 11 Aug 2021 22:49:01

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 ⬤

	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: 11 Aug 2021 22:49:01

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 ●

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: 11 Aug 2021 22:49:01

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

	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: 11 Aug 2021 22:49:01

TIMEPOINT	DAY 8
Select one response below to indicate the intensity of your **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 ◯
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: 11 Aug 2021 22:49:01

TIMEPOINT	DAY 8
Select one response below to indicate the intensity of your **FATIGUE**	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(8)

Generated On: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

| 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: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

| 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: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

| 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: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

| 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.

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: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

Is the participant continuing to the next visit?   Yes ●

                                                                                          No ◯

Continuing Flag   1

US3542090

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) **31 Jan 2021 19:18:44**

Generated On: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

| Is the participant continuing to the next visit? | Yes ● |
| | No ○ |

| Continuing Flag | 1 |

US3542090

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) **30 Mar 2021 21:36:09**

Generated On: 11 Aug 2021 22:49:01

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

SC WAS NOT CONDUCTED DUE
TO PARTICIPANT NOT
RECEIVING DOSE 2.

US3542090

Folder: Safety Call Day 43 (1)

Form: Continuing

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

Generated On: 11 Aug 2021 22:49:01

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3542090

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) **30 Mar 2021 21:36:09**

Generated On: 11 Aug 2021 22:49:01

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

SC WAS NOT CONDUCTED DUE TO PARTICIPANT NOT RECEIVING DOSE 2.

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: 11 Aug 2021 22:49:01

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) **18 Dec 2020 16:16:13**

Generated On: 11 Aug 2021 22:49:01

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	03 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

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

Generated On: 11 Aug 2021 22:49:01

Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	03 NOV 2020
Time of assessment *(00:00-23:59)*	12:42 (24 HR)
Vital Signs Date and Time (derived)	03 NOV 2020 12:42
Temperature *(xxx.x)*	98.4 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	76 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	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) **18 Dec 2020 16:16:13**

Generated On: 11 Aug 2021 22:49:01

Was the physical examination performed?   Yes ●

                                                                           No ○

Date of examination *(dd MMM yyyy)*   03 NOV 2020

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

| 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: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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 ≥ 100.4°F/38°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

Patient Cloud Close Date & Time	01 NOV 2020 23:59

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

TIMEPOINT	**DAY 78**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

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

Fever (Temperature ≥ 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: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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 ≥ 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 ◯

FDA-CBER-2022-1614-2665581

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

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 ≥ 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 ◯

FDA-CBER-2022-1614-2665583

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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: 11 Aug 2021 22:49:01

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 ≥ 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 ◯

FDA-CBER-2022-1614-2665585

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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: 11 Aug 2021 22:49:01

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

Date and time of submission	14 DEC 2020 10:59:54
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

FDA-CBER-2022-1614-2665587

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 DEC 2020 07:53:48
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: 11 Aug 2021 22:49:01

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 DEC 2020 10:24:07
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: 11 Aug 2021 22:49:01

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 JAN 2021 09:09:40
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: 11 Aug 2021 22:49:01

TIMEPOINT	DAY 138

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯

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

Date and time of submission	10 JAN 2021 08:30:51
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: 11 Aug 2021 22:49:01

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 ≥ 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 ⬡

FDA-CBER-2022-1614-2665592

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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: 11 Aug 2021 22:49:01

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 JAN 2021 00:19:50
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: 11 Aug 2021 22:49:01

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):

Symptom	
Fever (Temperature ≥ 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 ⭕

FDA-CBER-2022-1614-2665595

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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: 11 Aug 2021 22:49:01

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 ≥ 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 ◯

FDA-CBER-2022-1614-2665597

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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: 11 Aug 2021 22:49:01

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 ≥ 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: 11 Aug 2021 22:49:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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: 11 Aug 2021 22:49:01

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 FEB 2021 12:47:51
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: 11 Aug 2021 22:49:01

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 FEB 2021 11:08:53
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: 11 Aug 2021 22:49:01

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 MAR 2021 14:04:30
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3542090

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:49:01

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 11:09:07

US3542090

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) **10 Dec 2020 16:08:05**

Generated On: 11 Aug 2021 22:49:01

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

Data signed: (b) (4) **10 Dec 2020 16:08:05**

Generated On: 11 Aug 2021 22:49:01

Is the participant continuing to the next visit?   Yes ●

                                                                    No ◯

Continuing Flag   1

US3542090

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) **27 Dec 2020 22:59:52**

Generated On: 11 Aug 2021 22:49:01

| Was Contact Attempted? | Yes ● |
| | No ○ |

Date of Contact or Contact Attempt *(dd MMM yyyy)*	21 DEC 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 119 (1)

Form: Continuing

Data signed: (b) (4) **27 Dec 2020 22:59:52**

Generated On: 11 Aug 2021 22:49:01

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

Folder: Safety Call Day 149 (1)
Form: Safety Call
Data signed: (b) (4) **25 Jan 2021 20:41:27**
Generated On: 11 Aug 2021 22:49:01

| Was Contact Attempted? | Yes ● |
| | No ○ |

Date of Contact or Contact Attempt *(dd MMM yyyy)*	22 JAN 2021
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 149 (1)

Form: Continuing

Data signed: (b) (4) **25 Jan 2021 20:41:27**

Generated On: 11 Aug 2021 22:49:01

Is the participant continuing to the next visit? Yes ⬤

No ◯

Continuing Flag 1

US3542090

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) **23 Feb 2021 20:11:27**

Generated On: 11 Aug 2021 22:49:01

| Was Contact Attempted? | Yes ● |
| | No ○ |

Date of Contact or Contact Attempt *(dd MMM yyyy)*	22 FEB 2021
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 179 (1)

Form: Continuing

Data signed: (b) (4)   **16 Mar 2021 17:54:24**

Generated On: 11 Aug 2021 22:49:01

Is the participant continuing to the next visit?   Yes ◯

                                                                     No ⬤

Continuing Flag   _____

US3542090
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Data signed: (b) (4)   **10 Mar 2021 22:21:08**
Generated On: 11 Aug 2021 22:49:01

| Was this visit performed? | Yes ○ |
| | No ● |

Visit date (dd MMM yyyy) _____

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

| Folder OID | VISIT4 |

US3542090

Folder: Adverse Events

Form: Adverse Events Summary

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

Generated On: 11 Aug 2021 22:49:01

Did the participant experience any adverse events?   Yes ●

No ○

If Yes, enter details on the Adverse Events form.

Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **23 Feb 2021 16:41:28**
Generated On: 11 Aug 2021 22:49:01

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	

US3542090
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **23 Feb 2021 16:41:28**
Generated On: 11 Aug 2021 22:49:01

Persistent or significant disability or incapacity	False
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 Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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)*	15 JAN 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ◯
	Grade 2/Moderate ⬤
	Grade 3/Severe ◯
	Grade 4 ◯
Is the adverse event serious?	Yes ◯
	No ⬤
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ◯
	No ◯
	Unknown ◯
Number of Days in ICU	

US3542090

Folder: Adverse Events
Form: Adverse Events (2)
Data signed: (b) (4) 23 Feb 2021 16:41:28
Generated On: 11 Aug 2021 22:49:01

Persistent or significant disability or incapacity	False
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	False
Concomitant Medication	True
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 Ony)	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: 11 Aug 2021 22:49:01

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) **10 Mar 2021 18:40:48**

Generated On: 11 Aug 2021 22:49:01

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 ○

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
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) **10 Mar 2021 18:40:48**

Generated On: 11 Aug 2021 22:49:01

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 ○

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
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) **10 Mar 2021 18:40:48**
Generated On: 11 Aug 2021 22:49:01

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 ○

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
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 ●

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 ○

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Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
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) **10 Mar 2021 18:40:48**

Generated On: 11 Aug 2021 22:49:01

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 ○

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
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) **10 Mar 2021 18:40:48**

Generated On: 11 Aug 2021 22:49:01

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 ⚪

	Intramuscular ⭕
	Respiratory (Inhalation) ⭕
	Intralesional ⭕
	Intraperiteoneal ⭕
	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 ⭕

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Data signed: (b) (4) **10 Mar 2021 18:40:48**
Generated On: 11 Aug 2021 22:49:01

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) **10 Mar 2021 18:40:48**

Generated On: 11 Aug 2021 22:49:01

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
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)*	15 JAN 2021
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) **10 Mar 2021 18:40:48**

Generated On: 11 Aug 2021 22:49:01

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 ⭕

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EAB) (1725)

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Data signed: (b) (4) **10 Mar 2021 18:40:48**
Generated On: 11 Aug 2021 22:49:01

Intramuscular	○
Respiratory (Inhalation)	○
Intralesional	○
Intraperiteoneal	○
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)*	15 JAN 2021
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 ○

Name of Medication	INFLUENZA VACCINATION

Prophylaxis	Yes ●
	No ○

Indication	FLU PREVENTION

Dose per administration	0.5

Dose unit	mg ○
	ug ○
	mL ●
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ○

If dose unit is Other, specify	

Frequency	once daily ○
	twice daily ○
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ○
	once ●
	unknown ○
	other ○

If frequency is Other, specify	

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

Intramuscular	●
Respiratory (Inhalation)	○
Intralesional	○
Intraperiteoneal	○
Nasal	○
Vaginal	○
Rectal	○
Intravenous	○
Intravenous Bolus	○
Intravenous Drip	○
Other	○

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	02 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ○
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	02 NOV 2020
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 ○

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) **10 Mar 2021 18:40:48**

Generated On: 11 Aug 2021 22:49:01

Name of Medication	IBUPROFEN

Prophylaxis   Yes ◯

No ⬤

Indication	POLYARTHRALGIA
Dose per administration	800

Dose unit   mg ⬤

ug ◯

mL ◯

g ◯

IU ◯

tablet ◯

capsule ◯

puff ◯

Other ◯

If dose unit is Other, specify _____

Frequency   once daily ◯

twice daily ◯

three times daily ◯

four times daily ◯

every other day ◯

every week ◯

every month ◯

as needed ◯

once ⬤

unknown ◯

other ◯

If frequency is Other, specify _____

Route of administration   Oral ⬤

Topical ◯

Subcutaneous ◯

Transdermal ◯

Intraocular ◯

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	17 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤

If not Ongoing, End date *(dd MMM yyyy)*	17 OCT 2020
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

Data signed: (b) (4) **04 Feb 2021 22:33:04**

Generated On: 11 Aug 2021 22:49:01

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: 11 Aug 2021 22:49:01

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

Date of study discontinuation/completion *(dd MMM yyyy)*	10 MAR 2021

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

PARTICIPANT DOES NOT WANT TO RETURN TO CLINIC FOR DECISION VISIT AND JUST WANTS TO BE UNBLINDED OVER THE PHONE. PREFERS TO GET VACCINE OUTSIDE OF STUDY (DESPITE NOT KNOWING IF GOT VACCINE IN STUDY).

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: 11 Aug 2021 22:49:01

Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:55:44
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

Form: Participant Creation

Generated On: 11 Aug 2021 22:49:01

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:49:01

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:40:43
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'Yes (Y)'	Elissa Malkin (b) (4) (b) (4)	28 Aug 2020 16:14:33

US3542090

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:49:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:40:47
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '28 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 15:24:49

Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:40:47
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'Clinic (Clinic)'	Elissa Malkin (b) (4) (b) (4)	28 Aug 2020 16:14:33

US3542090
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:49:01
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered 'SCRN'	System	28 Aug 2020 16:14:33

US3542090

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:01

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:07
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
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: 11 Aug 2021 22:49:01

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:07
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '65'	Madhu Balachandran (b) (4)	31 Aug 2020 18:40:18

US3542090
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:49:01
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered 'YEARS'	System	31 Aug 2020 18:40:18

US3542090
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:49:01

Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '65'	System	28 Aug 2020 16:14:49

US3542090
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:49:01

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:07
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'Male (M)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:40:18

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:07
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:40:18

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:07
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '1'	Madhu Balachandran (b) (4)	31 Aug 2020 18:40:18

US3542090
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:49:01
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:07
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '0'	Madhu Balachandran (b) (4)	31 Aug 2020 18:40:18

US3542090

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:01

Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:07
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '0'	Madhu Balachandran (b) (4)	31 Aug 2020 18:40:18

US3542090

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:01

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:07
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '0'	Madhu Balachandran (b) (4)	31 Aug 2020 18:40:18

US3542090

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:01

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:07
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '0'	Madhu Balachandran (b) (4)	31 Aug 2020 18:40:18

US3542090

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:01

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:07
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '0'	Madhu Balachandran (b) (4)	31 Aug 2020 18:40:18

US3542090
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:49:01
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:07
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered empty.	Madhu Balachandran (b) (4)	31 Aug 2020 18:40:18

US3542090
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:49:01
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:07
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '0'	Madhu Balachandran (b) (4)	31 Aug 2020 18:40:18

US3542090
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:49:01
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:07
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '0'	Madhu Balachandran (b) (4)	31 Aug 2020 18:40:18

US3542090

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:01

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered '28 Aug 2020'	Elissa Malkin (b) (4)	28 Aug 2020 16:14:49

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Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:01

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered 'Aug 2020'	System	28 Aug 2020 16:14:49

US3542090
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:49:01
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '2020'	System	28 Aug 2020 16:14:49

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:45
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'Amendment 3 (3)'	Elissa Malkin (b) (4) (b) (4)	28 Aug 2020 16:14:49

US3542090

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:01

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered 'Yes (Y)'	Elissa Malkin (b) (4)	28 Aug 2020 16:14:49

US3542090

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:01

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:45
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered empty.	Elissa Malkin (b) (4) (b) (4)	28 Aug 2020 16:14:49

US3542090
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:49:01
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:45
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered empty.	Elissa Malkin (b) (4) (b) (4)	28 Aug 2020 16:14:49

US3542090

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:01

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:41:45
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'No (N)'	Elissa Malkin (b) (4) (b) (4)	28 Aug 2020 16:14:49

US3542090

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:01

If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 15:24:49

US3542090

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:01

Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '1'	System	28 Aug 2020 16:14:55

US3542090

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:49:01

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:45:47
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'Yes (Y)'	Elissa Malkin (b) (4) (b) (4)	28 Aug 2020 16:14:55

Folder: Screening
Form: Medical History Summary
Generated On: 11 Aug 2021 22:49:01

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:40:51

US3542090

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
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) (b) (4)	31 Aug 2020 18:41:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 18:41:38
Data point term sent to Coder	System	31 Aug 2020 18:41:15
User entered 'Sleep Apnea'	Madhu Balachandran (b) (4)	31 Aug 2020 18:41:09

US3542090

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered 'UN Aug 2019'	Madhu Balachandran (b) (4)	31 Aug 2020 18:41:09

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered '0'	Madhu Balachandran (b) (4)	31 Aug 2020 18:41:09

US3542090

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:01

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:41:09

US3542090

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered empty.	Madhu Balachandran (b) (4)	31 Aug 2020 18:41:09

US3542090

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:01

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered '0'	Madhu Balachandran (b) (4)	31 Aug 2020 18:41:09

US3542090

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:01

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered 'Aug 2019'	System	31 Aug 2020 18:41:09

US3542090

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:01

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '2019'	System	31 Aug 2020 18:41:09

US3542090
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:49:01

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered empty.	System	31 Aug 2020 18:41:09

US3542090
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:49:01

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered empty.	System	31 Aug 2020 18:41:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered 'UN Nov 2015'	Madhu Balachandran (b) (4)	31 Aug 2020 18:41:44

US3542090

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered '0'	Madhu Balachandran (b) (4)	31 Aug 2020 18:41:44

US3542090
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:49:01
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered 'No (N)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered 'UN Nov 2015'	Madhu Balachandran (b) (4)	31 Aug 2020 18:41:44

US3542090

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:01

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered '0'	Madhu Balachandran (b) (4)	31 Aug 2020 18:41:44

US3542090

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:01

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered 'Nov 2015'	System	31 Aug 2020 18:41:44

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '2015'	System	31 Aug 2020 18:41:44

US3542090
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:49:01
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered 'Nov 2015'	System	31 Aug 2020 18:41:44

US3542090

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:01

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '2015'	System	31 Aug 2020 18:41:44

US3542090

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered 'UN Aug 2011'	Madhu Balachandran (b) (4)	31 Aug 2020 18:42:10

US3542090

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered '0'	Madhu Balachandran (b) (4)	31 Aug 2020 18:42:10

US3542090

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:01

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered 'No (N)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:42:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered 'UN Aug 2011'	Madhu Balachandran (b) (4)	31 Aug 2020 18:42:10

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered '0'	Madhu Balachandran (b) (4)	31 Aug 2020 18:42:10

Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:49:01

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered 'Aug 2011'	System	31 Aug 2020 18:42:10

US3542090

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:01

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '2011'	System	31 Aug 2020 18:42:10

US3542090

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:01

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered 'Aug 2011'	System	31 Aug 2020 18:42:10

US3542090

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:01

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '2011'	System	31 Aug 2020 18:42:10

US3542090

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:53:12
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) (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) (b) (4)	03 Nov 2020 21:20:25
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:19:52
Data point term sent to Coder	System	03 Nov 2020 21:19:42
User entered 'Erectile dysfunction'	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:19:17

Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:49:01
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:53:12
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:19:52
User entered 'un UNK 2012'	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:19:17

US3542090

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:53:12
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:19:52
User entered '0'	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:19:17

Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:49:01
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:53:12
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:19:52
User entered 'Yes (Y)'	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:19:17

US3542090

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:53:12
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:19:52
User entered empty.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:19:17

US3542090

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:01

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:53:12
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:19:52
User entered '0'	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:19:17

US3542090
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:49:01
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered 'Jan 2012'	System	03 Nov 2020 21:19:17

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '2012'	System	03 Nov 2020 21:19:17

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered empty.	System	03 Nov 2020 21:19:17

US3542090

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:01

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered empty.	System	03 Nov 2020 21:19:17

US3542090

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:01

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:00:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:42:52

US3542090

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:01

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:00:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '28 Aug 2020'	Madhu Balachandran (b) (4)	31 Aug 2020 18:42:52

US3542090
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:00:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '10:51'	Madhu Balachandran (b) (4)	31 Aug 2020 18:42:52

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '28 Aug 2020 10:51'	System	31 Aug 2020 18:42:52

US3542090

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:01

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered '69' in (b) (4)	Madhu Balachandran	31 Aug 2020 18:42:52
DataPoint set to visible.	System (b) (4)	28 Aug 2020 16:14:55

US3542090
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:49:01

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered '187.8' lb	(b) (4) Madhu Balachandran	31 Aug 2020 18:42:52
DataPoint set to visible.	(b) (4) System	28 Aug 2020 16:14:55

US3542090
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:49:01
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered missing code ND - Not Done.	Madhu Balachandran (b) (4)	31 Aug 2020 18:42:52

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:00:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered empty.	Madhu Balachandran (b) (4)	31 Aug 2020 18:42:52

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:00:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered empty.	Madhu Balachandran (b) (4)	31 Aug 2020 18:42:52

US3542090
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:49:01
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered missing code ND - Not Done.	Madhu Balachandran (b) (4)	31 Aug 2020 18:42:52

US3542090
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:49:01
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered 'bpm'	System	31 Aug 2020 18:42:52

US3542090
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:49:01
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:00:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered missing code ND - Not Done.	Madhu Balachandran (b) (4)	31 Aug 2020 18:42:52

US3542090
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:49:01
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered 'breaths/min'	System	31 Aug 2020 18:42:52

US3542090

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:01

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:00:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered missing code ND - Not Done.	Madhu Balachandran (b) (4)	31 Aug 2020 18:42:52

US3542090
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:49:01
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered 'mmHg'	System	31 Aug 2020 18:42:52

US3542090
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:49:01
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:00:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered missing code ND - Not Done.	Madhu Balachandran (b) (4)	31 Aug 2020 18:42:52

US3542090
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:49:01
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered 'mmHg'	System	31 Aug 2020 18:42:52

US3542090
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:49:01
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

Folder: Screening
Form: Physical Examination
Generated On: 11 Aug 2021 22:49:01

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:30:59
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:16:13
DataPoint Un-verified.	Erika Faust (b) (4)	16 Dec 2020 17:24:41
Signature has been broken.	Erika Faust (b) (4)	16 Dec 2020 17:24:41
User entered 'Yes (Y)' reason for change: New Information	Erika Faust (b) (4)	16 Dec 2020 17:24:41
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
User entered 'No (N)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:42:55

US3542090

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:01

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:30:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Dec 2020 16:16:13
DataPoint Un-verified.	Erika Faust (b) (4) (b) (4)	16 Dec 2020 17:24:41
Signature has been broken.	Erika Faust (b) (4) (b) (4)	16 Dec 2020 17:24:41
User entered '28 Aug 2020' reason for change: New Information	Erika Faust (b) (4) (b) (4)	16 Dec 2020 17:24:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:00:51
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered empty.	Madhu Balachandran (b) (4)	31 Aug 2020 18:42:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered 'No (N)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:43:36

US3542090

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:01:23
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'No (N)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:43:36

US3542090

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered 'No (N)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:43:36

US3542090

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered 'No (N)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:43:36

Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:01:23
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'No (N)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:43:36

US3542090

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:01:23
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'No (N)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:43:36

US3542090

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered 'No (N)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:43:36

US3542090

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered 'No (N)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:01:23
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'No (N)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:43:36

US3542090

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered 'No (N)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:43:36

US3542090

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered 'No (N)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:43:36

US3542090

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:01

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:01:23
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:43:36

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:01:23
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'HOUSING INSPECTOR (office work only at this time)' reason for change: Data Entry Error	Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 18:48:28
User entered 'Housing Inspector'	Madhu Balachandran (b) (4)	31 Aug 2020 18:43:36

US3542090

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:01

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '0'	Madhu Balachandran (b) (4)	31 Aug 2020 18:43:36

Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:49:01
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:01:23
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '0'	Madhu Balachandran (b) (4)	31 Aug 2020 18:43:36

Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:49:01
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:01:23
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '0'	Madhu Balachandran (b) (4)	31 Aug 2020 18:43:36

US3542090

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:01:23
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '1'	Madhu Balachandran (b) (4)	31 Aug 2020 18:43:36

US3542090

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered '0'	Madhu Balachandran (b) (4)	31 Aug 2020 18:43:36

Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:49:01
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:01:23
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '0'	Madhu Balachandran (b) (4)	31 Aug 2020 18:43:36

Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:49:01
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '0'	Madhu Balachandran (b) (4)	31 Aug 2020 18:43:36

US3542090

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:01

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:01:23
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered empty.	Madhu Balachandran (b) (4)	31 Aug 2020 18:43:36

US3542090
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:49:01

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:42:37
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:44:25

US3542090

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:49:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:42:39
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '28 Aug 2020'	Madhu Balachandran (b) (4)	31 Aug 2020 18:44:25

US3542090

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:42:39
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'Clinic (Clinic)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:44:25

US3542090
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:49:01
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered 'VISIT1'	System	31 Aug 2020 18:44:25

US3542090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered '28 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 16:24:40

US3542090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:01

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:45:09
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '188349'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 16:24:40

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:01

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 16:24:40

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered 'No (N)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:44:35

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered 'No (N)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:44:35

Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:45:09
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'No (N)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:44:35

US3542090

Folder: Visit 1 Day 1

Form: Randomization

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Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:45:09
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'No (N)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:44:35

US3542090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:01

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered 'No (N)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:44:35

US3542090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:01

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:14
DataPoint Verified.	(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) (b) (4)	23 Sep 2020 15:02:28
User entered 'No (N)'	Hannah Yellin (b) (4) (b) (4)	23 Sep 2020 15:02:06
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: 11 Aug 2021 22:49:01

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered missing code ND - Not Done.	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:01

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered missing code ND - Not Done.	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:08

US3542090
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:49:01

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered missing code ND - Not Done.	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:08

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered missing code ND - Not Done.	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:08

US3542090
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:49:01
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User accepted default value 'Pre-Dose (PREDOSE)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:08

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:01

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '28 Aug 2020'	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '10:51'	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:01

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '28 Aug 2020 10:51'	System	31 Aug 2020 18:46:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:01

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '98.6' F	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:01

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'Oral (Oral)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:08

US3542090
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:49:01
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered empty.	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:08

US3542090
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:49:01
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '89'	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:08

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Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:49:01
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered 'bpm'	System	31 Aug 2020 18:46:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:01

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '16'	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:08

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Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:49:01
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered 'breaths/min'	System	31 Aug 2020 18:46:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:01

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '127'	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:01

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered 'mmHg'	System	31 Aug 2020 18:46:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:01

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered '72'	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered 'mmHg'	System	31 Aug 2020 18:46:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:01

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered missing code ND - Not Done.	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:01

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered missing code ND - Not Done.	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:08

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User accepted default value 'Post-Dose (POSTDOSE)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:01

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:01

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '28 Aug 2020'	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '13:38'	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:01

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '28 Aug 2020 13:38'	System	31 Aug 2020 18:46:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:01

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '98.2' F	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:08

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'Oral (Oral)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:01

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered empty.	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:08

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered '70'	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:08

US3542090
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:49:01
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered 'bpm'	System	31 Aug 2020 18:46:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:01

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '16'	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:01

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered 'breaths/min'	System	31 Aug 2020 18:46:08

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:48:39
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '110'	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:01

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered 'mmHg'	System	31 Aug 2020 18:46:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:01

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered '70'	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered 'mmHg'	System	31 Aug 2020 18:46:08

US3542090

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:01

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:31:06
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Dec 2020 16:16:13
DataPoint Un-verified.	Erika Faust (b) (4) (b) (4)	16 Dec 2020 17:25:07
Signature has been broken.	Erika Faust (b) (4) (b) (4)	16 Dec 2020 17:25:07
User entered 'No (N)' reason for change: New Information	Erika Faust (b) (4) (b) (4)	16 Dec 2020 17:25:07
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:49:36
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:13

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:01

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:31:06
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Dec 2020 16:16:13
DataPoint Un-verified.	Erika Faust (b) (4) (b) (4)	16 Dec 2020 17:25:07
Signature has been broken.	Erika Faust (b) (4) (b) (4)	16 Dec 2020 17:25:07
User entered empty; reason for change New Information	Erika Faust (b) (4) (b) (4)	16 Dec 2020 17:25:07
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:49:36
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '28 Aug 2020'	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:13

US3542090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:01

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:50:18
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'Yes (Y)'	Hira Qadir (b) (4) (b) (4)	28 Aug 2020 17:12:37

US3542090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:01

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered empty.	Hira Qadir (b) (4) (b) (4)	28 Aug 2020 17:12:37

US3542090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:50:33
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered empty.	Hira Qadir (b) (4) (b) (4)	28 Aug 2020 17:12:37

US3542090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:01

What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 17:12:37

Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:49:01

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered '28 Aug 2020'	(b) (4) Hira Qadir (b) (4) (b) (4)	28 Aug 2020 17:12:37

US3542090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered '13:08'	Hira Qadir (b) (4)	28 Aug 2020 17:12:37

US3542090
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:49:01

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '28 Aug 2020 13:08'	System	28 Aug 2020 17:12:37

US3542090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:01

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered 'Right Arm (RIGHT ARM)'	Hira Qadir (b) (4) (b) (4)	28 Aug 2020 17:12:37

Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:49:01

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 17:12:37

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:37

US3542090

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:01

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:52:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '28 Aug 2020'	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:37

US3542090

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:01

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:52:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '11:32'	Madhu Balachandran (b) (4)	31 Aug 2020 18:46:37

US3542090
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:49:01
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '28 Aug 2020 11:32'	System	31 Aug 2020 18:46:37

Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 11 Aug 2021 22:49:01
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered '28 Aug 2020'	Madhu Balachandran (b) (4)	31 Aug 2020 18:47:14

Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:49:01
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:47:14

Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:49:01

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:47:14

Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:49:01
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:53:06
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '11:51'	Madhu Balachandran (b) (4)	31 Aug 2020 18:47:14

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '28 Aug 2020 11:51'	System	31 Aug 2020 18:47:14

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:47:14

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered 'No (N)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:47:14

FDA-CBER-2022-1614-2665834

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:53:06
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered empty.	Madhu Balachandran (b) (4)	31 Aug 2020 18:47:14

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered empty.	System	31 Aug 2020 18:47:14

Folder: Visit 1 Day 1
Form: Continuing
Generated On: 11 Aug 2021 22:49:01

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:53:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:47:23

US3542090
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 11 Aug 2021 22:49:01
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '1'	System	31 Aug 2020 18:47:23

US3542090
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
User entered '28 Aug 2020 13:28'	System	28 Aug 2020 17:12:37

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 17:12:37

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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'	System	01 Sep 2020 21:53:33
User entered '97.7'	System	01 Sep 2020 21:53:33

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 17:12:37

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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'	System	02 Sep 2020 16:57:03
User entered '98.7'	System	02 Sep 2020 16:57:03

US3542090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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

FDA-CBER-2022-1614-2665907

US3542090
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:49:01
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
User entered '28 Aug 2020 16:53'	System	28 Aug 2020 17:12:37

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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-b462-1dceb2d22edd'	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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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

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US3542090
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:49:01
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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'	System	30 Aug 2020 16:08:25
User entered '30 Aug 2020 12:08'	System	30 Aug 2020 16:08:25

US3542090
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:49:01
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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

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US3542090
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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

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US3542090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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'	System	03 Sep 2020 16:36:08
User entered '03 Sep 2020 12:36'	System	03 Sep 2020 16:36:08

US3542090
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:49:01
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
User entered '28 Aug 2020 15:58'	System	28 Aug 2020 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
User entered '28 Aug 2020 16:53'	System	28 Aug 2020 17:12:37

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 17:12:37

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 17:12:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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

Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:49:01
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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

Folder: Diary Dose 1 (1)
Form: Headache_Day(8)
Generated On: 11 Aug 2021 22:49:01

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 16:36:50

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 16:36:50

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 16:36:50

Folder: Diary Dose 1 (1)
Form: JointsAche_Day(9)
Generated On: 11 Aug 2021 22:49:01

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 16:45:49

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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

Folder: Diary Dose 1 (1)
Form: JointsAche_Day(12)
Generated On: 11 Aug 2021 22:49:01
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 16:04:20

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 16:04:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 16:36:50

FDA-CBER-2022-1614-2666110

US3542090
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(9)
Generated On: 11 Aug 2021 22:49:01
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 16:45:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	08 Sep 2020 18:02:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 13:57:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	09 Sep 2020 01:45:22
User entered '4 Sep 2020'	Madhu Balachandran (b) (4)	08 Sep 2020 18:02:33

US3542090

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:01

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered 'Contact Made (CONTACT MADE)'	Madhu Balachandran (b) (4)	08 Sep 2020 18:02:33

US3542090
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:49:01
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered empty.	Madhu Balachandran (b) (4)	08 Sep 2020 18:02:33

US3542090

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:01

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:31:25
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:45:22
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	08 Sep 2020 18:02:24

US3542090
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:49:01
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '1'	System	08 Sep 2020 18:02:24

US3542090
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:49:01

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	14 Sep 2020 17:57:50

US3542090

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:29:38
User signature succeeded.	David Diemert (b) (4) (b) (4)	17 Sep 2020 04:22:23
User entered '11 Sep 2020'	Madhu Balachandran (b) (4)	14 Sep 2020 17:57:50

US3542090

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:01

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered 'Contact Made (CONTACT MADE)'	Madhu Balachandran (b) (4)	14 Sep 2020 17:57:50

US3542090
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:49:01
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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
User entered empty.	Madhu Balachandran (b) (4)	14 Sep 2020 17:57:50

US3542090

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:01

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:31:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	17 Sep 2020 04:22:23
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	14 Sep 2020 17:57:52

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '1'	System	14 Sep 2020 17:57:52

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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)'	Madhu Balachandran (b) (4)	22 Sep 2020 16:41:46

FDA-CBER-2022-1614-2666149

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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'	Madhu Balachandran (b) (4)	22 Sep 2020 16:41:46

US3542090

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:01

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 19:39:29
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 03:14:39
User entered 'Contact Made (CONTACT MADE)'	Madhu Balachandran (b) (4)	22 Sep 2020 16:41:46

US3542090

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:01

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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.	Madhu Balachandran (b) (4)	22 Sep 2020 16:41:46

Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:49:01

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 19:39:45
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 03:14:39
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	22 Sep 2020 16:41:28

US3542090
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:49:01

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '1'	System	22 Sep 2020 16:41:28

US3542090
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:49:01

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:21:37
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
User entered 'Yes (Y)'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:45:06

US3542090
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:49:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:21:37
User signature succeeded.	David Diemert (b) (4) (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) (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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:21:37
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
User entered 'Clinic (Clinic)'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:45:06

US3542090
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:49:01
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered 'VISIT2'	System	19 Oct 2020 18:45:06

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:01

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User accepted default value 'Pre-Dose (PREDOSE)'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:46:24

US3542090
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:49:01
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:21:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
User entered 'Yes (Y)'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:46:24

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:01

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:21:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
User entered '10 Oct 2020'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:46:24

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:21:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
User entered '13:02'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:46:24

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:01

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:21:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
User entered '98.2' F	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:46:24

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:01

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:21:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
User entered 'Oral (Oral)'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:46:24

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:01

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:21:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:46:24

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:01

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:21:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
User entered '79'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:46:24

US3542090
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:49:01
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered 'bpm'	System	19 Oct 2020 18:46:24

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:01

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:21:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
User entered '16'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:46:24

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:21:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
User entered '136'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:46:24

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:01

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered 'mmHg'	System	19 Oct 2020 18:46:24

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:01

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:21:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
User entered '78'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:46:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered 'mmHg'	System	19 Oct 2020 18:46:24

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:01

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User accepted default value 'Post-Dose (POSTDOSE)'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:46:24

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:21:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
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) (b) (4)	19 Oct 2020 18:46:30
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) (b) (4)	19 Oct 2020 18:46:24

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:01

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:21:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
User entered empty.	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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:21:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:46:24

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered empty.	System	19 Oct 2020 18:46:24

US3542090
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:49:01

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:21:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
User entered empty.	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: 11 Aug 2021 22:49:01
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:21:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
User entered empty.	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: 11 Aug 2021 22:49:01

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:21:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:46:24

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:21:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:46:24

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered empty.	System	19 Oct 2020 18:46:24

US3542090
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:49:01
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:21:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
User entered empty.	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: 11 Aug 2021 22:49:01
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered empty.	System	19 Oct 2020 18:46:24

US3542090
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:49:01

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:21:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
User entered empty.	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: 11 Aug 2021 22:49:01

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered empty.	System	19 Oct 2020 18:46:24

US3542090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:01

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:21:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
User entered empty.	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: 11 Aug 2021 22:49:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered empty.	System	19 Oct 2020 18:46:24

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:22:05
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
User entered 'Yes (Y)'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:46:40

FDA-CBER-2022-1614-2666191

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:22:05
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
User entered '10 Oct 2020'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:46:40

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:22:10
User signature succeeded.	David Diemert (b) (4) (b) (4)	14 Oct 2020 04:00:06
User entered 'No (N)'	David Diemert (b) (4) (b) (4)	10 Oct 2020 17:49:02

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:22:10
User signature succeeded.	David Diemert (b) (4) (b) (4)	14 Oct 2020 04:00:06
User entered 'Participant declined due to Adverse Event (ADVERSE EVENT)'	David Diemert (b) (4) (b) (4)	10 Oct 2020 17:49:02

US3542090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:22:10
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: 11 Aug 2021 22:49:01
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered empty.	System	10 Oct 2020 17:49:02

US3542090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:22:10
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

FDA-CBER-2022-1614-2666197

US3542090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:22:10
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: 11 Aug 2021 22:49:01

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered empty.	System	10 Oct 2020 17:49:02

US3542090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:01

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:22:10
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: 11 Aug 2021 22:49:01

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:22:10
User entered empty.	System	10 Oct 2020 17:49:02

US3542090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:01

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered empty.	System	10 Oct 2020 17:49:02

US3542090

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:01

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:22:14
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
User entered 'Yes (Y)'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:46:57

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:22:14
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
User entered '10 Oct 2020'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:46:57

FDA-CBER-2022-1614-2666204

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:22:14
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
User entered '13:13'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:46:57

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:22:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
User entered '10 Oct 2020'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:47:19

US3542090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:49:01

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:47:19

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:22:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
User entered 'Yes (Y)'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:47:19

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:22:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
User entered '13:15'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:47:19

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:47:19

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:22:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
User entered 'No (N)'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:47:19

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:22:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:47:19

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered empty.	System	19 Oct 2020 18:47:19

US3542090

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:01

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:22:28
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
User entered 'Yes (Y)'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:47:26

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '1'	System	19 Oct 2020 18:47:26

US3542090

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:01

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:55:00
User signature succeeded.	David Diemert (b) (4) (b) (4)	31 Jan 2021 19:18:44
User entered 'No (N)'	Hannah Yellin (b) (4) (b) (4)	26 Jan 2021 18:12:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:55:00
User signature succeeded.	David Diemert (b) (4) (b) (4)	31 Jan 2021 19:18:44
User entered empty.	Hannah Yellin (b) (4) (b) (4)	26 Jan 2021 18:12:57

US3542090
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:49:01
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:55:00
User signature succeeded.	David Diemert (b) (4) (b) (4)	31 Jan 2021 19:18:44
User entered empty.	Hannah Yellin (b) (4) (b) (4)	26 Jan 2021 18:12:57

US3542090
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:49:01
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:55:00
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:18:44
User entered empty.	Hannah Yellin (b) (4)	26 Jan 2021 18:12:57

US3542090
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:49:01

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 20:56:16
User closed query 'Please complete Safety Call page.' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 20:56:13
Query 'Please complete Safety Call page.' answered with 'Completed' (Site from CRA).	Hannah Yellin (b) (4) (b) (4)	26 Jan 2021 18:14:19
User opened query 'Please complete Safety Call page.' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 18:08:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	04 Nov 2020 18:40:51

US3542090
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:49:01
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '1'	System	04 Nov 2020 18:40:51

US3542090
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:49:01

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 14:39:38
User closed query 'Please confirm. No source filed.' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 14:39:36
Query 'Please confirm. No source filed.' answered with 'Not done as participant did not receive Dose 2 at Day 29 visit (withdrawn from receiving further doses).' (Site from CRA).	David Diemert (b) (4) (b) (4)	26 Mar 2021 21:50:18
User opened query 'Please confirm. No source filed.' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 14:32:31
User signature succeeded.	David Diemert (b) (4) (b) (4)	31 Jan 2021 19:18:44
User entered 'No (N)'	Hannah Yellin (b) (4) (b) (4)	26 Jan 2021 18:13:05

US3542090
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:49:01
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 14:39:38
User signature succeeded.	David Diemert (b) (4) (b) (4)	31 Jan 2021 19:18:44
User entered empty.	Hannah Yellin (b) (4) (b) (4)	26 Jan 2021 18:13:05

US3542090

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:01

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 14:39:38
User signature succeeded.	David Diemert (b) (4) (b) (4)	31 Jan 2021 19:18:44
User entered empty.	Hannah Yellin (b) (4) (b) (4)	26 Jan 2021 18:13:05

US3542090
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:49:01
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 14:39:38
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Mar 2021 21:36:09
Signature has been broken.	(b) (4), (b) (6)	30 Mar 2021 18:17:48
User entered 'SC was not conducted due to participant not receiving dose 2.' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 18:17:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	31 Jan 2021 19:18:44
User entered empty.	Hannah Yellin (b) (4) (b) (4)	26 Jan 2021 18:13:05

US3542090

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:01

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:32:36
User closed query 'Please complete Safety Call page.' (Site from CRA).	(b) (4), (b) (6)	28 Feb 2021 17:35:48
Query 'Please complete Safety Call page.' answered with 'Completed' (Site from CRA).	Hannah Yellin (b) (4) (b) (4)	26 Jan 2021 18:14:07
User opened query 'Please complete Safety Call page.' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 18:08:19
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	04 Nov 2020 18:40:56

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '1'	System	04 Nov 2020 18:40:56

US3542090

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:01

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User closed query 'Please confirm. No source filed.' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 15:24:10
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 14:39:11
Query 'Please confirm. No source filed.' answered with 'Not done as participant did not receive Dose 2 at Day 29 visit.' (Site from CRA).	David Diemert (b) (4) (b) (4)	26 Mar 2021 21:49:29
User opened query 'Please confirm. No source filed.' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 14:33:08
User signature succeeded.	David Diemert (b) (4) (b) (4)	31 Jan 2021 19:18:44
User entered 'No (N)'	Hannah Yellin (b) (4) (b) (4)	26 Jan 2021 18:13:14

US3542090
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:49:01
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 14:39:11
User signature succeeded.	David Diemert (b) (4) (b) (4)	31 Jan 2021 19:18:44
User entered empty.	Hannah Yellin (b) (4) (b) (4)	26 Jan 2021 18:13:14

US3542090

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:01

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 14:39:11
User signature succeeded.	David Diemert (b) (4) (b) (4)	31 Jan 2021 19:18:44
User entered empty.	Hannah Yellin (b) (4) (b) (4)	26 Jan 2021 18:13:14

US3542090

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:01

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 14:39:11
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Mar 2021 21:36:09
Signature has been broken.	(b) (4), (b) (6)	30 Mar 2021 18:16:57
User entered 'SC was not conducted due to participant not receiving dose 2.' reason for change: New Information	(b) (4), (b) (6)	30 Mar 2021 18:16:57
User signature succeeded.	David Diemert (b) (4) (b) (4)	31 Jan 2021 19:18:44
User entered empty.	Hannah Yellin (b) (4) (b) (4)	26 Jan 2021 18:13:14

US3542090

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:01

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 20:33:45
User closed query 'Please complete Safety Call page.' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 20:33:33
Query 'Please complete Safety Call page.' answered with 'Completed' (Site from CRA).	Hannah Yellin (b) (4) (b) (4)	26 Jan 2021 18:13:40
User opened query 'Please complete Safety Call page.' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 18:08:25
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	04 Nov 2020 18:41:02

US3542090
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:49:01
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '1'	System	04 Nov 2020 18:41:02

US3542090
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:49:01

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:08:30
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	04 Nov 2020 18:41:16

US3542090

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:08:30
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Dec 2020 16:16:13
Signature has been broken.	Erika Faust (b) (4) (b) (4)	16 Dec 2020 17:09:16
User entered '03 Nov 2020' reason for change: Data Entry Error	Erika Faust (b) (4) (b) (4)	16 Dec 2020 17:09:16
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered '3 Nov 2020'	Erika Faust (b) (4) (b) (4)	04 Nov 2020 18:41:16

US3542090

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:08:30
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered 'Clinic (Clinic)'	Erika Faust (b) (4) (b) (4)	04 Nov 2020 18:41:16

US3542090
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:49:01
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered 'VISIT3'	System	04 Nov 2020 18:41:16

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:08:39
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:14
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	04 Nov 2020 18:41:45

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:08:39
User signature succeeded.	David Diemert (b) (4) (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) (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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:08:39
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:14
User entered '12:42'	Erika Faust (b) (4)	04 Nov 2020 18:41:45

US3542090
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:49:01
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:08:39
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:14
User entered '98.4' F	Erika Faust (b) (4) (b) (4)	04 Nov 2020 18:41:45

US3542090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:01

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:08:39
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:14
User entered 'Oral (Oral)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 18:41:45

US3542090
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:49:01
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:08:39
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:14
User entered empty.	Erika Faust (b) (4) (b) (4)	04 Nov 2020 18:41:45

US3542090
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:49:01

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:08:39
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:14
User entered '76'	Erika Faust (b) (4) (b) (4)	04 Nov 2020 18:41:45

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered 'bpm'	System	04 Nov 2020 18:41:45

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:08:39
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:14
User entered '12'	Erika Faust (b) (4) (b) (4)	04 Nov 2020 18:41:45

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered 'breaths/min'	System	04 Nov 2020 18:41:45

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:08:39
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:14
User entered '135'	Erika Faust (b) (4) (b) (4)	04 Nov 2020 18:41:45

US3542090
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:49:01
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered 'mmHg'	System	04 Nov 2020 18:41:45

US3542090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:01

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:08:39
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:14
User entered '83'	Erika Faust (b) (4) (b) (4)	04 Nov 2020 18:41:45

US3542090
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:49:01
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered 'mmHg'	System	04 Nov 2020 18:41:45

US3542090
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:49:01

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:49:01

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:01

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:08:51
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	04 Nov 2020 18:41:53

US3542090

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:01

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:08:51
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Dec 2020 16:16:13
Signature has been broken.	Erika Faust (b) (4) (b) (4)	16 Dec 2020 17:09:35
User entered '03 Nov 2020' reason for change: Data Entry Error	Erika Faust (b) (4) (b) (4)	16 Dec 2020 17:09:35
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered '3 Nov 2020'	Erika Faust (b) (4) (b) (4)	04 Nov 2020 18:41:53

Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:49:01

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:08:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	04 Nov 2020 18:41:59

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:08:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered empty.	Erika Faust (b) (4) (b) (4)	04 Nov 2020 18:41:59

US3542090

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:01

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:08:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered empty.	Erika Faust (b) (4) (b) (4)	04 Nov 2020 18:41:59

US3542090

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:01

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered empty.	System	04 Nov 2020 18:41:59

US3542090

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:01

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:09:00
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	04 Nov 2020 18:42:09

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '1'	System	04 Nov 2020 18:42:09

US3542090
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
User closed query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 10:18:07
Query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'Participant had vague arthralgias that were not consistent with COVID-19 on questioning by a medical professional. This has been recorded as an AE.' (Site from DM).	David Diemert (b) (4) (b) (4)	14 Jan 2021 20:52:25
User opened query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 15:39:40
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: 11 Aug 2021 22:49:01

Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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

FDA-CBER-2022-1614-2666271

US3542090
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: 11 Aug 2021 22:49:01
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:45:41
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: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:47:26
Data entry locked.	System	28 Aug 2020 17:12:37
User entered 'Day 78'	System	28 Aug 2020 17:12:37

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:47:26

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:47:26

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:47:26

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:47:26

US3542090
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01

Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:47:26

US3542090
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:47:26

US3542090
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:47:26

US3542090
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:47:26

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:47:26

US3542090
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:47:26

US3542090
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:47:26

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:47:26

US3542090
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:47:26

US3542090
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:47:26

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:47:26

US3542090
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01

Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:47:26

US3542090
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:47:26

US3542090
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:47:26

US3542090
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:47:26

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:47:26

US3542090
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:47:26

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:47:26

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:47:26

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:47:26

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:47:26

US3542090

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:47:26
Data entry locked.	System	28 Aug 2020 17:12:37
User entered '11 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: 11 Aug 2021 22:49:01

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:47:26
Data entry locked.	System	28 Aug 2020 17:12:37
User entered '15 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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-12-14T10:59:41', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '2b9bdb0f-f084-4d86-b612-a4c865cb95ef'	System	14 Dec 2020 15:59:58
User entered 'No (N)'	System	14 Dec 2020 15:59:58

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-12-14T10:58:38', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '2b9bdb0f-f084-4d86-b612-a4c865cb95ef'	System	14 Dec 2020 15:59:58
User entered 'No (N)'	System	14 Dec 2020 15:59:58

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-12-14T10:59:54', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '2b9bdb0f-f084-4d86-b612-a4c865cb95ef'	System	14 Dec 2020 15:59:58
User entered '14 Dec 2020 10:59:54'	System	14 Dec 2020 15:59:58

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-12-20T07:53:32', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '1337f602-fb8f-4488-bd2f-2ebeb0d482cf'	System	20 Dec 2020 12:53:51
User entered 'No (N)'	System	20 Dec 2020 12:53:51

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-12-20T07:53:41', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '1337f602-fb8f-4488-bd2f-2ebeb0d482cf'	System	20 Dec 2020 12:53:51
User entered 'No (N)'	System	20 Dec 2020 12:53:51

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-12-20T07:53:48', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '1337f602-fb8f-4488-bd2f-2ebeb0d482cf'	System	20 Dec 2020 12:53:51
User entered '20 Dec 2020 07:53:48'	System	20 Dec 2020 12:53:51

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-12-27T10:24:00', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'f2b0b11e-94f9-47c6-9d9b-cd8ac6dd8ec8'	System	27 Dec 2020 15:24:10
User entered 'No (N)'	System	27 Dec 2020 15:24:10

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-12-27T10:24:04', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'f2b0b11e-94f9-47c6-9d9b-cd8ac6dd8ec8'	System	27 Dec 2020 15:24:10
User entered 'No (N)'	System	27 Dec 2020 15:24:10

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2020-12-27T10:24:07', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'f2b0b11e-94f9-47c6-9d9b-cd8ac6dd8ec8'	System	27 Dec 2020 15:24:10
User entered '27 Dec 2020 10:24:07'	System	27 Dec 2020 15:24:10

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2021-01-03T09:09:33', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '84d8d596-63b6-4c36-9b5f-17e0e88bd831'	System	03 Jan 2021 14:09:43
User entered 'No (N)'	System	03 Jan 2021 14:09:43

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2021-01-03T09:09:36', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '84d8d596-63b6-4c36-9b5f-17e0e88bd831'	System	03 Jan 2021 14:09:43
User entered 'No (N)'	System	03 Jan 2021 14:09:43

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2021-01-03T09:09:40', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '84d8d596-63b6-4c36-9b5f-17e0e88bd831'	System	03 Jan 2021 14:09:43
User entered '03 Jan 2021 09:09:40'	System	03 Jan 2021 14:09:43

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2021-01-10T08:30:38', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '9f8c99fa-cff8-4124-a8fe-2a5534c85cf9'	System	10 Jan 2021 13:30:54
User entered 'No (N)'	System	10 Jan 2021 13:30:54

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2021-01-10T08:30:45', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '9f8c99fa-cff8-4124-a8fe-2a5534c85cf9'	System	10 Jan 2021 13:30:54
User entered 'No (N)'	System	10 Jan 2021 13:30:54

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2021-01-10T08:30:51', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '9f8c99fa-cff8-4124-a8fe-2a5534c85cf9'	System	10 Jan 2021 13:30:54
User entered '10 Jan 2021 08:30:51'	System	10 Jan 2021 13:30:54

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01

Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2021-01-24T00:19:42', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '3d885bbb-56ae-47f4-b3df-bc0b372597b8'	System	24 Jan 2021 05:19:53
User entered 'No (N)'	System	24 Jan 2021 05:19:53

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2021-01-24T00:19:46', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '3d885bbb-56ae-47f4-b3df-bc0b372597b8'	System	24 Jan 2021 05:19:53
User entered 'No (N)'	System	24 Jan 2021 05:19:53

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2021-01-24T00:19:50', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '3d885bbb-56ae-47f4-b3df-bc0b372597b8'	System	24 Jan 2021 05:19:53
User entered '24 Jan 2021 00:19:50'	System	24 Jan 2021 05:19:53

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

FDA-CBER-2022-1614-2666494

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01

Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

FDA-CBER-2022-1614-2666535

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2021-02-23T12:47:41', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '15f29398-9499-472f-954c-3256f55ac04a'	System	23 Feb 2021 19:10:09
User entered 'No (N)'	System	23 Feb 2021 19:10:09

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2021-02-23T12:47:45', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '15f29398-9499-472f-954c-3256f55ac04a'	System	23 Feb 2021 19:10:09
User entered 'No (N)'	System	23 Feb 2021 19:10:09

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2021-02-23T12:47:51', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: '15f29398-9499-472f-954c-3256f55ac04a'	System	23 Feb 2021 19:10:09
User entered '23 Feb 2021 12:47:51'	System	23 Feb 2021 19:10:09

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2021-02-28T06:08:42-05:00', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'b414513e-8243-4759-b692-3469ab6d1032'	System	28 Feb 2021 11:08:55
User entered 'No (N)'	System	28 Feb 2021 11:08:55

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2021-02-28T06:08:49-05:00', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'b414513e-8243-4759-b692-3469ab6d1032'	System	28 Feb 2021 11:08:55
User entered 'No (N)'	System	28 Feb 2021 11:08:55

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2021-02-28T06:08:53-05:00', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'b414513e-8243-4759-b692-3469ab6d1032'	System	28 Feb 2021 11:08:55
User entered '28 Feb 2021 11:08:53'	System	28 Feb 2021 11:08:55

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2021-03-07T09:04:22-05:00', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'bc3683e6-976d-49eb-b64b-8f8f71c9f8f8'	System	07 Mar 2021 14:04:32
User entered 'No (N)'	System	07 Mar 2021 14:04:32

US3542090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2021-03-07T09:04:25-05:00', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'bc3683e6-976d-49eb-b64b-8f8f71c9f8f8'	System	07 Mar 2021 14:04:32
User entered 'No (N)'	System	07 Mar 2021 14:04:32

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2021-03-07T09:04:30-05:00', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'bc3683e6-976d-49eb-b64b-8f8f71c9f8f8'	System	07 Mar 2021 14:04:32
User entered '07 Mar 2021 14:04:30'	System	07 Mar 2021 14:04:32

US3542090
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:49:01
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:49:01

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2021-02-28T06:09:02-05:00', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'bfc4e371-edc6-4d31-9aaf-bb352c74c727'	System	28 Feb 2021 11:09:10
User entered 'No (N)'	System	28 Feb 2021 11:09:10

US3542090

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:49:01

Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91BDE2D9-91FD-4576-A503-F53201482CC2)', Time: '2021-02-28T06:09:07-05:00', User OID: 'PatientReportedOutcome (US3542090)', ODM File OID: 'bfc4e371-edc6-4d31-9aaf-bb352c74c727'	System	28 Feb 2021 11:09:10
User entered '28 Feb 2021 11:09:07'	System	28 Feb 2021 11:09:10

US3542090

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:01

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:15:12
User signature succeeded.	David Diemert (b) (4) (b) (4)	10 Dec 2020 16:08:05
User entered 'No (N)'	Madhu Balachandran (b) (4)	01 Dec 2020 21:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:15:12
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:08:05
User entered empty.	Madhu Balachandran (b) (4)	01 Dec 2020 21:05:43

US3542090

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:01

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:15:12
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:08:05
User entered empty.	Madhu Balachandran (b) (4)	01 Dec 2020 21:05:43

US3542090
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:49:01
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:15:12
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:08:05
User entered empty.	Madhu Balachandran (b) (4)	01 Dec 2020 21:05:43

US3542090

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:01

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:15:16
User signature succeeded.	David Diemert (b) (4) (b) (4)	10 Dec 2020 16:08:05
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	01 Dec 2020 21:05:46

US3542090
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:49:01
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '1'	System	01 Dec 2020 21:05:46

US3542090
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:49:01

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:15:22
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:59:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:53:37

US3542090

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:15:22
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:59:53
User entered '21 Dec 2020'	(b) (4), (b) (6)	22 Dec 2020 16:53:37

US3542090
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:49:01
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:15:22
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:59:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Dec 2020 16:53:37

US3542090

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:01

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:15:22
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:59:53
User entered empty.	(b) (4), (b) (6)	22 Dec 2020 16:53:37

US3542090

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:01

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:15:27
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:59:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Dec 2020 16:53:42

US3542090
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:49:01
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '1'	System	22 Dec 2020 16:53:42

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:41:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 18:27:03

FDA-CBER-2022-1614-2666590

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:15:32
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:41:27
User entered '22 Jan 2021'	(b) (4), (b) (6)	25 Jan 2021 18:27:03

FDA-CBER-2022-1614-2666591

US3542090

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:01

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:15:32
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Jan 2021 20:41:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Jan 2021 18:27:03

US3542090

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:01

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:15:32
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Jan 2021 20:41:27
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 18:27:03

US3542090
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:49:01

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:15:36
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Jan 2021 20:41:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 18:27:08

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '1'	System	25 Jan 2021 18:27:08

US3542090
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:49:01

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:33:41
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Feb 2021 20:11:27
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	23 Feb 2021 18:09:05

US3542090

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:33:41
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Feb 2021 20:11:27
User entered '22 Feb 2021'	Taylor Ladson (b) (4) (b) (4)	23 Feb 2021 18:09:05

Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:49:01
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:33:41
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Feb 2021 20:11:27
User entered 'Contact Made (CONTACT MADE)'	Taylor Ladson (b) (4) (b) (4)	23 Feb 2021 18:09:05

FDA-CBER-2022-1614-2666598

US3542090
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:49:01
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:33:41
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Feb 2021 20:11:27
User entered empty.	Taylor Ladson (b) (4) (b) (4)	23 Feb 2021 18:09:05

US3542090

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:01

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:33:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Mar 2021 17:54:24
Signature has been broken.	Hannah Yellin (b) (4) (b) (4)	16 Mar 2021 16:49:02
User entered 'No (N)' reason for change: New Information	Hannah Yellin (b) (4) (b) (4)	16 Mar 2021 16:49:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Feb 2021 20:11:27
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	23 Feb 2021 18:08:58

US3542090
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:49:01
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered empty.	System	16 Mar 2021 16:49:02
User entered '1'	System	23 Feb 2021 18:08:58

US3542090
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:49:01

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:33:58
User signature succeeded.	David Diemert (b) (4) (b) (4)	10 Mar 2021 22:21:08
User entered 'No (N)'	David Diemert (b) (4) (b) (4)	10 Mar 2021 22:20:49

US3542090
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:49:01
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:33:58
User signature succeeded.	David Diemert (b) (4) (b) (4)	10 Mar 2021 22:21:08
User entered empty.	David Diemert (b) (4) (b) (4)	10 Mar 2021 22:20:49

US3542090

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:33:58
User signature succeeded.	David Diemert (b) (4) (b) (4)	10 Mar 2021 22:21:08
User entered empty.	David Diemert (b) (4) (b) (4)	10 Mar 2021 22:20:49

US3542090
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:49:01
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered 'VISIT4'	System	10 Mar 2021 22:20:49

US3542090

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:49:01

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:49
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	14 Sep 2020 17:58:32

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:49:01

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (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.	Coder Import (b) (4) (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: 11 Aug 2021 22:49:01

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	17 Sep 2020 04:22:23
User entered 'No (N)'	Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:01

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	17 Sep 2020 04:22:23
User entered 'No (N)'	Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:01

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
User entered 'No (N)'	Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:01

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
User entered '4 Sep 2020'	Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
User entered empty.	Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

FDA-CBER-2022-1614-2666613

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered empty.	System	14 Sep 2020 17:59:17

FDA-CBER-2022-1614-2666614

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:01

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
User entered 'No (N)'	Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:01

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
User entered '4 Sep 2020'	Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:01

End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	17 Sep 2020 04:22:23
User entered empty.	Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered empty.	System	14 Sep 2020 17:59:17

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	17 Sep 2020 04:22:23
User entered 'Grade 1/Mild (Grade 1/Mild)'	Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:01

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	17 Sep 2020 04:22:23
User entered 'No (N)'	Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
User entered '0'	Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:01

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
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

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	17 Sep 2020 04:22:23
User entered '0'	Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:01

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
User entered empty.	Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:01

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	17 Sep 2020 04:22:23
User entered empty.	Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:01

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
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: 11 Aug 2021 22:49:01

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	17 Sep 2020 04:22:23
User entered empty.	Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:01

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
User entered '0'	Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:01

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
User entered '0'	Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:01

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
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: 11 Aug 2021 22:49:01

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	17 Sep 2020 04:22:23
User entered 'Not Related (NOT RELATED)'	Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

US3542090
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:49:01
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	17 Sep 2020 04:22:23
User entered 'Not Related (NOT RELATED)'	Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:01

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	17 Sep 2020 04:22:23
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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:01

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
User entered '1'	Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:01

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
User entered '0'	Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:01

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	17 Sep 2020 04:22:23
User entered '0'	Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:01

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	17 Sep 2020 04:22:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:22:23
User entered empty.	Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:49:01
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	17 Sep 2020 04:22:23
User entered empty.	Madhu Balachandran (b) (4)	14 Sep 2020 17:59:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:01

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '0'	System	14 Sep 2020 17:59:17

US3542090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:01

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '0'	System	14 Sep 2020 17:59:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:01

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

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Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 22:49:01
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:01

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
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: 11 Aug 2021 22:49:01

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:22:10
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) (b) (4)	03 Nov 2020 21:05:41
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) (b) (4)	19 Oct 2020 18:49:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:01

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
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).	(b) (4), (b) (6)	06 Nov 2020 05:56:51
User signature succeeded.	David Diemert (b) (4) (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).	(b) (4), (b) (6)	02 Nov 2020 11:27:47
User entered 'No (N)'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:49:35

Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 22:49:01

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:22:10
User entered 'No (N)'	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: 11 Aug 2021 22:49:01

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
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).	(b) (4), (b) (6)	06 Nov 2020 05:59:04
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:22:10
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) (b) (4)	03 Nov 2020 21:13:09
User entered '03 Sep 2020' reason for change: Data Entry Error	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:13:03
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).	(b) (4), (b) (6)	02 Nov 2020 11:27:58
User entered '04 Sep 2020'	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: 11 Aug 2021 22:49:01

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:22:10
User entered empty.	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: 11 Aug 2021 22:49:01

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered empty.	System	19 Oct 2020 18:49:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:01

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:35:45
User signature succeeded.	David Diemert (b) (4)	23 Feb 2021 16:41:28
DataPoint Un-verified.	Erika Faust (b) (4) (b) (4)	22 Feb 2021 17:55:01
Signature has been broken.	Erika Faust (b) (4) (b) (4)	22 Feb 2021 17:55:01
User entered 'No (N)' reason for change: New Information	Erika Faust (b) (4) (b) (4)	22 Feb 2021 17:55:01
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 09:08:47
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' answered with 'ongoing' (Site from DM).	Elissa Malkin (b) (4) (b) (4)	21 Dec 2020 18:56:53
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 23:02:56
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:22:10
User entered 'Yes (Y)'	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: 11 Aug 2021 22:49:01

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:35:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Feb 2021 16:41:28
DataPoint Un-verified.	Erika Faust (b) (4) (b) (4)	22 Feb 2021 17:55:01
Signature has been broken.	Erika Faust (b) (4) (b) (4)	22 Feb 2021 17:55:01
User entered '15 Jan 2021' reason for change: New Information	Erika Faust (b) (4) (b) (4)	22 Feb 2021 17:55:01
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:22:10
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:49:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:22:10
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:49:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered empty.	System	19 Oct 2020 18:49:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:01

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
Signature has been broken.	Erika Faust (b) (4) (b) (4)	04 Nov 2020 18:49:20
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Erika Faust (b) (4) (b) (4)	04 Nov 2020 18:49:20
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:22:10
User entered 'Grade 1/Mild (Grade 1/Mild)'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:49:35

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:22:10
User entered 'No (N)'	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: 11 Aug 2021 22:49:01

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:22:10
User entered '0'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:49:35

US3542090
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 22:49:01
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:22:10
User entered '0'	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: 11 Aug 2021 22:49:01

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:22:10
User entered '0'	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: 11 Aug 2021 22:49:01

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:22:10
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:49:35

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:22:10
User entered empty.	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: 11 Aug 2021 22:49:01

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:22:10
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:49:35

US3542090
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 22:49:01
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:22:10
User entered empty.	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: 11 Aug 2021 22:49:01

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:22:10
User entered '0'	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: 11 Aug 2021 22:49:01

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:22:10
User entered '0'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:49:35

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:22:10
User entered '0'	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: 11 Aug 2021 22:49:01

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:22:10
User entered 'Not Related (NOT RELATED)'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:49:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:22:10
User entered 'Not Related (NOT RELATED)'	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: 11 Aug 2021 22:49:01

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:22:10
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	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: 11 Aug 2021 22:49:01

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:00:20
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:59:53
User closed query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Medications (#7 & 8) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 04:32:36
Query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Medications (#7 & 8) recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'Corrected to con med' (Site from DM).	Erika Faust (b) (4) (b) (4)	04 Dec 2020 16:31:51
DataPoint Un-verified.	Erika Faust (b) (4) (b) (4)	04 Dec 2020 16:31:40
Signature has been broken.	Erika Faust (b) (4) (b) (4)	04 Dec 2020 16:31:40
User entered '0' reason for change: Per Query Resolution	Erika Faust (b) (4) (b) (4)	04 Dec 2020 16:31:40
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User opened query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Medications (#7 & 8) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 15:01:22
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:22:10
User entered '1'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:49:35

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Folder: Adverse Events

Form: Adverse Events (2)

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Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:00:37
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:59:53
DataPoint Un-verified.	Erika Faust (b) (4) (b) (4)	04 Dec 2020 16:31:40
Signature has been broken.	Erika Faust (b) (4) (b) (4)	04 Dec 2020 16:31:40
User entered '1' reason for change: Per Query Resolution	Erika Faust (b) (4) (b) (4)	04 Dec 2020 16:31:40
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:22:10
User entered '0'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:49:35

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Generated On: 11 Aug 2021 22:49:01

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:22:10
User entered '0'	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: 11 Aug 2021 22:49:01

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 14:32:37
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Feb 2021 16:41:28
DataPoint Un-verified.	Erika Faust (b) (4) (b) (4)	22 Feb 2021 17:55:01
Signature has been broken.	Erika Faust (b) (4) (b) (4)	22 Feb 2021 17:55:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Erika Faust (b) (4) (b) (4)	22 Feb 2021 17:55:01
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:22:10
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	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: 11 Aug 2021 22:49:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:22:10
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 18:49:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:19:48
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:22:10
User entered empty.	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: 11 Aug 2021 22:49:01

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '0'	System	19 Oct 2020 18:49:35

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '1'	System	03 Nov 2020 21:05:41

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:01

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:34:41
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'Yes (Y)'	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: 11 Aug 2021 22:49:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
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

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:49:01

Name of Medication

Audit	User	Time (GMT)
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: 11 Aug 2021 22:49:01

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:01

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
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) (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) (b) (4)	03 Nov 2020 21:14:18
Signature has been broken.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:14:11
User entered 'General health prophylaxis' reason for change: Per Query Resolution	David Diemert (b) (4) (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) (b) (4)	05 Sep 2020 21:33:30
User entered 'Over the Counter'	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: 11 Aug 2021 22:49:01

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'UNK'	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: 11 Aug 2021 22:49:01

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'Other (OTHER)'	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: 11 Aug 2021 22:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'Unknown'	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: 11 Aug 2021 22:49:01

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'once daily (QD)'	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: 11 Aug 2021 22:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered empty.	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: 11 Aug 2021 22:49:01

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'Oral (ORAL)'	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: 11 Aug 2021 22:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered empty.	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: 11 Aug 2021 22:49:01

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'UN Aug 2019'	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: 11 Aug 2021 22:49:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered '0'	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: 11 Aug 2021 22:49:01

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'Yes (Y)'	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: 11 Aug 2021 22:49:01

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered empty.	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: 11 Aug 2021 22:49:01

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'No (N)'	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: 11 Aug 2021 22:49:01

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '1'	System	31 Aug 2020 18:35:52

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '1'	System	31 Aug 2020 18:35:52

FDA-CBER-2022-1614-2666697

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:01

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '804 (804)'	System	31 Aug 2020 18:35:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
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: 11 Aug 2021 22:49:01

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
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) (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) (b) (4)	11 Nov 2020 17:07:17
Signature has been broken.	Hannah Yellin (b) (4) (b) (4)	11 Nov 2020 17:07:10
User entered 'Yes (Y)' reason for change: New Information	Hannah Yellin (b) (4) (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) (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: 11 Aug 2021 22:49:01

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
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) (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) (b) (4)	03 Nov 2020 21:15:02
Signature has been broken.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:14:57
User entered 'General health prophylaxis' reason for change: Per Query Resolution	David Diemert (b) (4) (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) (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: 11 Aug 2021 22:49:01

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'UNK'	Madhu Balachandran (b) (4)	31 Aug 2020 18:36:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:01

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'Other (OTHER)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:36:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:01

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'once daily (QD)'	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: 11 Aug 2021 22:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered empty.	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: 11 Aug 2021 22:49:01

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'Oral (ORAL)'	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: 11 Aug 2021 22:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered empty.	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: 11 Aug 2021 22:49:01

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'UN Aug 2019'	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: 11 Aug 2021 22:49:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '0'	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: 11 Aug 2021 22:49:01

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'Yes (Y)'	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: 11 Aug 2021 22:49:01

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered empty.	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: 11 Aug 2021 22:49:01

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'No (N)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:36:44

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '1'	System	31 Aug 2020 18:36:44

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US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:01

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
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) (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) (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) (b) (4)	03 Nov 2020 21:15:31
User signature succeeded.	David Diemert (b) (4) (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) (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) (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: 11 Aug 2021 22:49:01

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
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) (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) (b) (4)	11 Nov 2020 17:07:32
Signature has been broken.	Hannah Yellin (b) (4) (b) (4)	11 Nov 2020 17:07:25
User entered 'Yes (Y)' reason for change: New Information	Hannah Yellin (b) (4) (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) (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: 11 Aug 2021 22:49:01

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
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) (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) (b) (4)	03 Nov 2020 21:15:36
Signature has been broken.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:15:31
User entered 'General health prophylaxis' reason for change: New Information	David Diemert (b) (4) (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) (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: 11 Aug 2021 22:49:01

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'UNK'	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: 11 Aug 2021 22:49:01

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'Other (OTHER)'	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: 11 Aug 2021 22:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'Unknown'	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: 11 Aug 2021 22:49:01

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'once daily (QD)'	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: 11 Aug 2021 22:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered empty.	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: 11 Aug 2021 22:49:01

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'Oral (ORAL)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:37:17

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:49:01
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered empty.	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: 11 Aug 2021 22:49:01

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'UN Aug 2019'	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: 11 Aug 2021 22:49:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered '0'	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: 11 Aug 2021 22:49:01

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'Yes (Y)'	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: 11 Aug 2021 22:49:01

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered empty.	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: 11 Aug 2021 22:49:01

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
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: 11 Aug 2021 22:49:01

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
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	System	03 Nov 2020 21:16:37
Coding entries removed.	David Diemert (b) (4) (b) (4)	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	System	31 Aug 2020 18:38:11
User entered 'Garlic Pills'	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: 11 Aug 2021 22:49:01

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
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.' answered with 'Updated to yes' (Site from DM).	Hannah Yellin (b) (4) (b) (4)	11 Nov 2020 17:07:47
Signature has been broken.	Hannah Yellin (b) (4) (b) (4)	11 Nov 2020 17:07:40
User entered 'Yes (Y)' reason for change: New Information	Hannah Yellin (b) (4) (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) (b) (4)	05 Sep 2020 21:33:30
User entered 'No (N)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:37:48

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
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) (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) (b) (4)	03 Nov 2020 21:15:52
Signature has been broken.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:15:47
User entered 'General health prophylaxis' reason for change: New Information	David Diemert (b) (4) (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) (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: 11 Aug 2021 22:49:01

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'UNK'	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: 11 Aug 2021 22:49:01

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'Other (OTHER)'	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: 11 Aug 2021 22:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'Unknown'	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: 11 Aug 2021 22:49:01

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'once daily (QD)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:37:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered empty.	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: 11 Aug 2021 22:49:01

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'Oral (ORAL)'	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: 11 Aug 2021 22:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered empty.	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: 11 Aug 2021 22:49:01

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'UN Aug 2019'	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: 11 Aug 2021 22:49:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered '0'	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: 11 Aug 2021 22:49:01

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'Yes (Y)'	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: 11 Aug 2021 22:49:01

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered empty.	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: 11 Aug 2021 22:49:01

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'No (N)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:37:48

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
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	System	03 Nov 2020 21:18:41
Coding entries removed.	David Diemert (b) (4) (b) (4)	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	System	31 Aug 2020 18:39:12
User entered 'Multivitamin'	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: 11 Aug 2021 22:49:01

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:59:25
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Dec 2020 16:16:13
DataPoint Un-verified.	Erika Faust (b) (4) (b) (4)	16 Dec 2020 17:11:53
Signature has been broken.	Erika Faust (b) (4) (b) (4)	16 Dec 2020 17:11:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Erika Faust (b) (4) (b) (4)	16 Dec 2020 17:11:53
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'No (N)'	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: 11 Aug 2021 22:49:01

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:22:10
Signature has been broken.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:18:32
User entered 'General health prophylaxis' reason for change: New Information	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:18:32
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'Over the counter - General Health'	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: 11 Aug 2021 22:49:01

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'UNK'	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: 11 Aug 2021 22:49:01

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'Other (OTHER)'	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: 11 Aug 2021 22:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'Unknown'	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: 11 Aug 2021 22:49:01

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'once daily (QD)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:38:26

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 11 Aug 2021 22:49:01
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered empty.	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: 11 Aug 2021 22:49:01

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4), (b) (4)	05 Sep 2020 21:33:30
User entered 'Oral (ORAL)'	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: 11 Aug 2021 22:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered empty.	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: 11 Aug 2021 22:49:01

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'UN Aug 2019' reason for change: Data Entry Error	Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 18:50:40
User entered 'UN UNK 2019'	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: 11 Aug 2021 22:49:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered '0'	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: 11 Aug 2021 22:49:01

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'Yes (Y)'	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: 11 Aug 2021 22:49:01

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered empty.	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: 11 Aug 2021 22:49:01

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'No (N)'	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: 11 Aug 2021 22:49:01

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered '1'	System	31 Aug 2020 18:38:26

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (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.	Coder Import (b) (4) (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: 11 Aug 2021 22:49:01

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'No (N)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:39:07

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
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

FDA-CBER-2022-1614-2666773

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 11 Aug 2021 22:49:01
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '100'	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: 11 Aug 2021 22:49:01

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'mg (mg)'	Madhu Balachandran (b) (4)	31 Aug 2020 18:39:07

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 11 Aug 2021 22:49:01
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered empty.	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: 11 Aug 2021 22:49:01

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered 'as needed (PRN)'	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: 11 Aug 2021 22:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered empty.	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: 11 Aug 2021 22:49:01

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'Oral (ORAL)'	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: 11 Aug 2021 22:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered empty.	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: 11 Aug 2021 22:49:01

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'UN Jul 2012'	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: 11 Aug 2021 22:49:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered '0'	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: 11 Aug 2021 22:49:01

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'Yes (Y)'	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: 11 Aug 2021 22:49:01

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 21:33:30
User entered empty.	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: 11 Aug 2021 22:49:01

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:33:30
User entered 'No (N)'	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: 11 Aug 2021 22:49:01

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered empty.	System	31 Aug 2020 18:39:07

FDA-CBER-2022-1614-2666788

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (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.	Coder Import (b) (4) (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: 11 Aug 2021 22:49:01

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered 'No (N)'	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: 11 Aug 2021 22:49:01

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered 'Polyarthralgias'	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: 11 Aug 2021 22:49:01

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered '5'	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: 11 Aug 2021 22:49:01

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered 'mg (mg)'	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: 11 Aug 2021 22:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered empty.	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: 11 Aug 2021 22:49:01

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered 'as needed (PRN)'	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: 11 Aug 2021 22:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered empty.	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: 11 Aug 2021 22:49:01

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered 'Oral (ORAL)'	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: 11 Aug 2021 22:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered empty.	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: 11 Aug 2021 22:49:01

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered '13 Oct 2020'	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: 11 Aug 2021 22:49:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered '0'	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: 11 Aug 2021 22:49:01

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:34:53
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 07:51:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	10 Mar 2021 18:40:49
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'Updated.' (Site from DM).	David Diemert (b) (4) (b) (4)	10 Mar 2021 17:37:11
DataPoint Un-verified.	David Diemert (b) (4) (b) (4)	10 Mar 2021 17:36:58
Signature has been broken.	David Diemert (b) (4) (b) (4)	10 Mar 2021 17:36:58
User entered 'No (N)' reason for change: New Information	David Diemert (b) (4) (b) (4)	10 Mar 2021 17:36:58
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 05:28:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered 'Yes (Y)'	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: 11 Aug 2021 22:49:01

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:34:56
User signature succeeded.	David Diemert (b) (4) (b) (4)	10 Mar 2021 18:40:49
DataPoint Un-verified.	David Diemert (b) (4) (b) (4)	10 Mar 2021 17:36:58
Signature has been broken.	David Diemert (b) (4) (b) (4)	10 Mar 2021 17:36:58
User entered '15 Jan 2021' reason for change: New Information	David Diemert (b) (4) (b) (4)	10 Mar 2021 17:36:58
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered empty.	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: 11 Aug 2021 22:49:01

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered 'No (N)'	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: 11 Aug 2021 22:49:01

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered empty.	System	04 Nov 2020 18:46:51

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered empty.	System	04 Nov 2020 18:46:51

FDA-CBER-2022-1614-2666805

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:01

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (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.	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: 11 Aug 2021 22:49:01

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered 'No (N)'	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: 11 Aug 2021 22:49:01

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered 'Polyarthralgias'	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: 11 Aug 2021 22:49:01

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered '500'	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: 11 Aug 2021 22:49:01

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered 'mg (mg)'	Erika Faust (b) (4) (b) (4)	04 Nov 2020 18:47:31

FDA-CBER-2022-1614-2666811

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered empty.	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: 11 Aug 2021 22:49:01

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered 'as needed (PRN)'	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: 11 Aug 2021 22:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered empty.	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: 11 Aug 2021 22:49:01

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered 'Oral (ORAL)'	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: 11 Aug 2021 22:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered empty.	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: 11 Aug 2021 22:49:01

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered '13 Oct 2020'	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: 11 Aug 2021 22:49:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered '0'	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: 11 Aug 2021 22:49:01

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:35:03
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 07:51:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	10 Mar 2021 18:40:49
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'Updated.' (Site from DM).	David Diemert (b) (4) (b) (4)	10 Mar 2021 17:37:38
DataPoint Un-verified.	David Diemert (b) (4) (b) (4)	10 Mar 2021 17:37:26
Signature has been broken.	David Diemert (b) (4) (b) (4)	10 Mar 2021 17:37:26
User entered 'No (N)' reason for change: New Information	David Diemert (b) (4) (b) (4)	10 Mar 2021 17:37:26
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 05:29:08
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered 'Yes (Y)'	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: 11 Aug 2021 22:49:01

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:35:05
User signature succeeded.	David Diemert (b) (4) (b) (4)	10 Mar 2021 18:40:49
DataPoint Un-verified.	David Diemert (b) (4) (b) (4)	10 Mar 2021 17:37:26
Signature has been broken.	David Diemert (b) (4) (b) (4)	10 Mar 2021 17:37:26
User entered '15 Jan 2021' reason for change: New Information	David Diemert (b) (4) (b) (4)	10 Mar 2021 17:37:26
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered empty.	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: 11 Aug 2021 22:49:01

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 19:20:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Nov 2020 21:48:53
User entered 'No (N)'	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: 11 Aug 2021 22:49:01

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
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: 11 Aug 2021 22:49:01

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered empty.	System	04 Nov 2020 18:47:31

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:59:25
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:59:53
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 17:03:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 17:03:44
Data point term sent to Coder	System	22 Dec 2020 17:02:50
User entered 'Influenza Vaccination'	(b) (4), (b) (6)	22 Dec 2020 17:02:25

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:01

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:59:25
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:59:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Dec 2020 17:02:25

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:01

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:59:25
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:59:53
User entered 'Flu Prevention'	(b) (4), (b) (6)	22 Dec 2020 17:02:25

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:01

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:59:25
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:59:53
User entered '0.5'	(b) (4), (b) (6)	22 Dec 2020 17:02:25

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:01

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:59:25
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:59:53
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:02:25

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:59:25
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:59:53
User entered empty.	(b) (4), (b) (6)	22 Dec 2020 17:02:25

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:01

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:59:25
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:59:53
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:02:25

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:59:25
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:59:53
User entered empty.	(b) (4), (b) (6)	22 Dec 2020 17:02:25

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:01

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:59:25
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:59:53
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	22 Dec 2020 17:02:25

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:59:25
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:59:53
User entered empty.	(b) (4), (b) (6)	22 Dec 2020 17:02:25

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:01

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:59:25
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:59:53
User entered '02 Nov 2020'	(b) (4), (b) (6)	22 Dec 2020 17:02:25

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:59:25
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:59:53
User entered '0'	(b) (4), (b) (6)	22 Dec 2020 17:02:25

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:01

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:59:25
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:59:53
User entered 'No (N)'	(b) (4), (b) (6)	22 Dec 2020 17:02:25

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:01

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:59:25
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:59:53
User entered '02 Nov 2020'	(b) (4), (b) (6)	22 Dec 2020 17:02:25

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:01

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:59:25
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:59:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:02:25

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:01

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered empty.	System	22 Dec 2020 17:02:25

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered empty.	System	22 Dec 2020 17:02:25

FDA-CBER-2022-1614-2666841

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:01

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered empty.	System	22 Dec 2020 17:02:25

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:35:13
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 10:18:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 10:18:54
User signature succeeded.	David Diemert (b) (4) (b) (4)	06 Mar 2021 00:42:15
Data point term sent to Coder	System	05 Mar 2021 16:53:35
User entered 'Ibuprofen'	Erika Faust (b) (4) (b) (4)	05 Mar 2021 16:52:55

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:01

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:35:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	06 Mar 2021 00:42:15
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	05 Mar 2021 16:52:55

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:01

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:35:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	06 Mar 2021 00:42:15
User entered 'Polyarthralgia'	Erika Faust (b) (4) (b) (4)	05 Mar 2021 16:52:55

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:01

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:35:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	06 Mar 2021 00:42:15
User entered '800'	Erika Faust (b) (4) (b) (4)	05 Mar 2021 16:52:55

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:01

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:35:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	06 Mar 2021 00:42:15
User entered 'mg (mg)'	Erika Faust (b) (4) (b) (4)	05 Mar 2021 16:52:55

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:35:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	06 Mar 2021 00:42:15
User entered empty.	Erika Faust (b) (4) (b) (4)	05 Mar 2021 16:52:55

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:01

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:35:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	06 Mar 2021 00:42:15
User entered 'once (ONCE)'	Erika Faust (b) (4) (b) (4)	05 Mar 2021 16:52:55

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:35:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	06 Mar 2021 00:42:15
User entered empty.	Erika Faust (b) (4) (b) (4)	05 Mar 2021 16:52:55

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:01

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:35:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	06 Mar 2021 00:42:15
User entered 'Oral (ORAL)'	Erika Faust (b) (4) (b) (4)	05 Mar 2021 16:52:55

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:35:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	06 Mar 2021 00:42:15
User entered empty.	Erika Faust (b) (4) (b) (4)	05 Mar 2021 16:52:55

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:01

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:35:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	06 Mar 2021 00:42:15
User entered '17 Oct 2020'	Erika Faust (b) (4) (b) (4)	05 Mar 2021 16:52:55

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:35:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	06 Mar 2021 00:42:15
User entered '0'	Erika Faust (b) (4) (b) (4)	05 Mar 2021 16:52:55

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:01

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:35:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	06 Mar 2021 00:42:15
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	05 Mar 2021 16:52:55

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 11 Aug 2021 22:49:01
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:35:13
User signature succeeded.	David Diemert (b) (4)	06 Mar 2021 00:42:15
User entered '17 Oct 2020'	Erika Faust (b) (4)	05 Mar 2021 16:52:55

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:01

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:35:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	06 Mar 2021 00:42:15
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	05 Mar 2021 16:52:55

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:01

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered empty.	System	05 Mar 2021 16:52:55

US3542090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:01

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered empty.	System	05 Mar 2021 16:52:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:01

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
User entered empty.	System	05 Mar 2021 16:52:55

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:49:01

Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 20:42:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	04 Feb 2021 22:33:04
User entered 'No (N)'	Hannah Yellin (b) (4) (b) (4)	03 Feb 2021 19:17:09

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:49:01

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:36:05
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
User entered '10 Oct 2020'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 19:36:53

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:49:01

Primary reason for dosing discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:37:55
Query 'Please confirm. Per PI progress note 10Mar2021 withdraw was not due to AE.' canceled (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 14:37:13
User opened query 'Please confirm. Per PI progress note 10Mar2021 withdraw was not due to AE.' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 14:36:39
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:36:13
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:36:05
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:37:38
User entered 'AE (specify) (ADVERSE EVENT)'	DeEnna Wedding (b) (4) (b) (4)	19 Oct 2020 19:36:53

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:37:55
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 14:36:16
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:36:05
User signature succeeded.	David Diemert (b) (4) (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), (b) (6)	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) (b) (4)	18 Nov 2020 16:43:59
Signature has been broken.	Hannah Yellin (b) (4) (b) (4)	18 Nov 2020 16:43:49
User entered 'AE #2' reason for change: Per Query Resolution	Hannah Yellin (b) (4) (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) (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) (b) (4)	19 Oct 2020 19:36:53

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:49:01

Date of study discontinuation/completion *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:36:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	10 Mar 2021 22:22:37
User entered '10 Mar 2021'	David Diemert (b) (4) (b) (4)	10 Mar 2021 22:18:48

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:49:01

Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:36:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	10 Mar 2021 22:22:37
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	David Diemert (b) (4) (b) (4)	10 Mar 2021 22:18:48

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:36:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	10 Mar 2021 22:22:37
User entered 'Participant does not want to return to clinic for Decision Visit and just wants to be unblinded over the phone. Prefers to get vaccine outside of study (despite not knowing if got vaccine in study).'	David Diemert (b) (4) (b) (4)	10 Mar 2021 22:18:48

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:49:01

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:36:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	10 Mar 2021 22:22:37
User entered empty.	David Diemert (b) (4) (b) (4)	10 Mar 2021 22:18:48

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:49:01

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:36:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	10 Mar 2021 22:22:37
User entered empty.	David Diemert (b) (4) (b) (4)	10 Mar 2021 22:18:48

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Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 22:49:01
Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:36:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	10 Mar 2021 22:22:37
User entered empty.	David Diemert (b) (4) (b) (4)	10 Mar 2021 22:18:48

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:49:01

Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:00:04
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 14:36:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	10 Mar 2021 22:22:37
User entered empty.	David Diemert (b) (4) (b) (4)	10 Mar 2021 22:18:48