

US3542030 (Prod: George Washington University)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:12:08

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US3542030

Form: Participant Creation

Data signed: (b) (4) 27 Aug 2020 15:36:35

Generated On: 10 Jun 2021 08:12:08

[Participant ID](#)

US3542030

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

US3542030

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 27 Aug 2020 15:36:35

Generated On: 10 Jun 2021 08:12:08

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	20 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 27 Aug 2020 15:36:35

Generated On: 10 Jun 2021 08:12:08

Date of Birth (MMM yyyy)	(b) (6) 1963
Age	56
Age Units	YEARS
Age (Derived)	56
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☒ Not Hispanic or Latino ☐ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 27 Aug 2020 15:36:35

Generated On: 10 Jun 2021 08:12:08

Date of Informed Consent (<i>dd MMM yyyy</i>)	20 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☒
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 27 Aug 2020 15:36:35

Generated On: 10 Jun 2021 08:12:08

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 27 Aug 2020 15:36:35

Generated On: 10 Jun 2021 08:12:08

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 27 Dec 2020 22:57:30

Generated On: 10 Jun 2021 08:12:08

Condition	MILD INTERMITTENT ASTHMA
Start date (dd MMM yyyy)	UN UNK 1975
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 1975
Start Year (derived)	1975
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3542030

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 27 Dec 2020 22:57:30

Generated On: 10 Jun 2021 08:12:08

Condition	DIABETES MELLITUS
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3542030

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 27 Dec 2020 22:57:30

Generated On: 10 Jun 2021 08:12:08

Condition	CHOLECYSTECTOMY
Start date (dd MMM yyyy)	UN MAY 1996
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN MAY 1996
Stop date completely unknown	False
Start Month and Year (derived)	MAY 1996
Start Year (derived)	1996
Stop Month and Year (derived)	MAY 1996
Stop Year (derived)	1996

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 27 Dec 2020 22:57:30

Generated On: 10 Jun 2021 08:12:08

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3542030

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 27 Dec 2020 22:57:30

Generated On: 10 Jun 2021 08:12:08

Condition	COMMON BILE DUCT STENT AND REPAIR
Start date (dd MMM yyyy)	UN MAY 1996
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN MAY 1996
Stop date completely unknown	False
Start Month and Year (derived)	MAY 1996
Start Year (derived)	1996
Stop Month and Year (derived)	MAY 1996
Stop Year (derived)	1996

US3542030

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 27 Dec 2020 22:57:30

Generated On: 10 Jun 2021 08:12:08

Condition	LEFT KNEE REPLACEMENT DUE TO OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN OCT 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN OCT 2019
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2019
Start Year (derived)	2019
Stop Month and Year (derived)	OCT 2019
Stop Year (derived)	2019

US3542030

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 27 Dec 2020 22:57:30

Generated On: 10 Jun 2021 08:12:08

Condition	OSTEOARTHRITIS OF KNEES
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 27 Dec 2020 22:57:30

Generated On: 10 Jun 2021 08:12:08

Condition	RENAL CALCULI
Start date (dd MMM yyyy)	23 JUL 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	23 JUL 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUL 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 27 Dec 2020 22:57:30

Generated On: 10 Jun 2021 08:12:08

Condition	INFREQUENT MIGRAINE HEADACHE
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Start Year (derived)	1998
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 27 Dec 2020 22:57:30

Generated On: 10 Jun 2021 08:12:08

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 27 Dec 2020 22:57:30

Generated On: 10 Jun 2021 08:12:08

Condition	DENTAL CARIES
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 27 Aug 2020 15:36:35

Generated On: 10 Jun 2021 08:12:08

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	11:57 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 11:57
Height (xxx.x)	65 in
Weight (xxx.x)	289 lb
BMI (xxx.x)	48.19267 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) 13 Dec 2020 19:24:50

Generated On: 10 Jun 2021 08:12:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 27 Aug 2020 15:36:35

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Date of assessment (dd MMM yyyy) 20 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 27 Aug 2020 15:36:35

Generated On: 10 Jun 2021 08:12:08

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (<i>dd MMM yyyy</i>)	20 AUG 2020
Test performed	Urine ☒
	Serum ☐
Result	Positive ☐
	Negative ☒
Was FSH sample collected?	Yes ☐
	No ☒
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 27 Aug 2020 15:36:35

Generated On: 10 Jun 2021 08:12:08

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

OFFICE ADMINISTRATOR

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) 27 Aug 2020 15:36:35

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 27 Aug 2020 15:36:35

Generated On: 10 Jun 2021 08:12:08

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	20 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) 29 Sep 2020 04:14:17

Generated On: 10 Jun 2021 08:12:08

What was the date of randomization? (dd MMM yyyy) 20 AUG 2020

What was the participant's randomization number? 143744

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) 27 Aug 2020 15:36:35

Generated On: 10 Jun 2021 08:12:08

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 27 Aug 2020 15:36:35

Generated On: 10 Jun 2021 08:12:08

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	11:57 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 11:57
Temperature (xxx.x)	98 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 27 Aug 2020 15:36:35

Generated On: 10 Jun 2021 08:12:08

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	13:36 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 13:36
Temperature (xxx.x)	98 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Dec 2020 19:24:50

Generated On: 10 Jun 2021 08:12:08

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 10 Dec 2020 16:07:55

Generated On: 10 Jun 2021 08:12:08

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 27 Aug 2020 15:36:35

Generated On: 10 Jun 2021 08:12:08

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 20 AUG 2020

What was the treatment time? (00:00-23:59) 13:06 (24 HR)

Treatment Date and Time (derived) 20 AUG 2020 13:06

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) 27 Aug 2020 15:36:35

Generated On: 10 Jun 2021 08:12:08

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	20 AUG 2020
Collection time (00:00-23:59)	12:57 (24 HR)
Collection date and time (derived)	20 AUG 2020 12:57

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 27 Aug 2020 15:36:35

Generated On: 10 Jun 2021 08:12:08

Collection date (dd MMM yyyy)			20 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:29	20 AUG 2020 12:29
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 27 Aug 2020 15:36:35

Generated On: 10 Jun 2021 08:12:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

20 AUG 2020 13:46

PC Open Date & Time

20 AUG 2020 13:26

PC Close Date & Time

20 AUG 2020 15:56

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

20 AUG 2020 16:51

PC Close Date & Time

21 AUG 2020 11:59

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

21 AUG 2020 13:24

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 15:38

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 12:34

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 13:11

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

25 AUG 2020 13:16

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

26 AUG 2020 16:35

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 13:28

PC Open Date & Time

20 AUG 2020 13:26

PC Close Date & Time

20 AUG 2020 15:56

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

PC Open Date & Time

20 AUG 2020 16:51

PC Close Date & Time

21 AUG 2020 11:59

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 13:19

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 15:38

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 12:32

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 13:12

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 13:17

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 16:36

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 13:27
PC Open Date & Time	20 AUG 2020 13:26
PC Close Date & Time	20 AUG 2020 15:56

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

- None ☐
- No interference with activity ☐
- Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐
- Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

NAUSEA/VOMITING

- None ☐
- No interference with activity or
1-2 episodes/24 hours ☐
- Some interference with activity
or >2 episodes/24 hours ☐
- Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

- None ☐
- No interference with activity ☐
- Some interference with activity
not requiring medical attention ☐
- Prevents daily activity and
requires medical attention ☐

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

20 AUG 2020 16:51

PC Close Date & Time

21 AUG 2020 11:59

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:08

Yes ☐	
PC Time stamp	21 AUG 2020 13:20
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

57 of 3457

EAB) (1725)

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:08

Yes ☐	
PC Time stamp	22 AUG 2020 15:39
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

59 of 3457

EAB) (1725)

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:08

Yes ☐	
PC Time stamp	23 AUG 2020 12:31
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:08

Yes ☐	
PC Time stamp	24 AUG 2020 13:12
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

63 of 3457

EAB) (1725)

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:08

Yes ☐	
PC Time stamp	25 AUG 2020 13:18
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

65 of 3457

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:08

Yes ☐	
PC Time stamp	26 AUG 2020 16:37
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3542030

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Sep 2020 15:27:04

Generated On: 10 Jun 2021 08:12:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542030

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 05 Sep 2020 15:27:04

Generated On: 10 Jun 2021 08:12:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542030

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 09 Sep 2020 01:41:06

Generated On: 10 Jun 2021 08:12:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542030

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 09 Sep 2020 01:41:06

Generated On: 10 Jun 2021 08:12:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542030

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Sep 2020 04:15:17

Generated On: 10 Jun 2021 08:12:08

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3542030

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 17 Sep 2020 04:15:17

Generated On: 10 Jun 2021 08:12:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542030

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 29 Sep 2020 04:14:17

Generated On: 10 Jun 2021 08:12:08

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	24 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3542030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Sep 2020 04:14:17

Generated On: 10 Jun 2021 08:12:08

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	24 SEP 2020
Time of assessment (00:00-23:59)	09:10 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 09:10
Temperature (xxx.x)	98.2 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3542030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Sep 2020 04:14:17

Generated On: 10 Jun 2021 08:12:08

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	24 SEP 2020
Time of assessment (00:00-23:59)	11:13 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 11:13
Temperature (xxx.x)	98.4 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3542030

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Sep 2020 04:14:17

Generated On: 10 Jun 2021 08:12:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 SEP 2020

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

US3542030

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 29 Sep 2020 04:14:17

Generated On: 10 Jun 2021 08:12:08

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (<i>dd MMM yyyy</i>)	24 SEP 2020
Test performed	Urine ☒
	Serum ☐
Result	Positive ☐
	Negative ☒
Was FSH sample collected?	Yes ☐
	No ☒
Collection date	
Collection time	
Collection date and time (derived)	

US3542030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 29 Sep 2020 04:14:17

Generated On: 10 Jun 2021 08:12:08

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 24 SEP 2020

What was the treatment time? (00:00-23:59) 10:40 (24 HR)

Treatment Date and Time (derived) 24 SEP 2020 10:40

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

US3542030

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Sep 2020 04:14:17

Generated On: 10 Jun 2021 08:12:08

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 SEP 2020

Collection time (00:00-23:59)

09:50 (24 HR)

Collection date and time (derived)

24 SEP 2020 09:50

US3542030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 29 Sep 2020 04:14:17

Generated On: 10 Jun 2021 08:12:08

Collection date (dd MMM yyyy)			24 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:58	24 SEP 2020 09:58
Nasopharyngeal Swab 2	No		

US3542030

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 29 Sep 2020 04:14:17

Generated On: 10 Jun 2021 08:12:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 11:13

PC Open Date & Time

24 SEP 2020 11:00

PC Close Date & Time

24 SEP 2020 13:30

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.4 °F

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

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

PC Time Stamp	24 SEP 2020 22:28
PC Open Date & Time	24 SEP 2020 14:25
PC Close Date & Time	25 SEP 2020 11:59

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 14:16

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

26 SEP 2020 12:40

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 15:01

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 13:52

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 6

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

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

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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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 12:12

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 13:45

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 11:17

PC Open Date & Time

24 SEP 2020 11:00

PC Close Date & Time

24 SEP 2020 13:30

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 22:07

PC Open Date & Time

24 SEP 2020 14:25

PC Close Date & Time

25 SEP 2020 11:59

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 14:17

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 12:33

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 14:58

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 13:29

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 12:04

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 13:44

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 11:18
PC Open Date & Time	24 SEP 2020 11:00
PC Close Date & Time	24 SEP 2020 13:30

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some

interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 22:08
PC Open Date & Time	24 SEP 2020 14:25
PC Close Date & Time	25 SEP 2020 11:59

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:08

Yes ☐	
PC Time stamp	25 SEP 2020 14:15
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:08

Yes ☐	
PC Time stamp	26 SEP 2020 12:32
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:08

Yes ☐	
PC Time stamp	27 SEP 2020 14:58
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:08

Yes ☐	
PC Time stamp	28 SEP 2020 13:29
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:08

Yes ☐	
PC Time stamp	29 SEP 2020 12:03
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:08

Yes ☐	
PC Time stamp	30 SEP 2020 13:44
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3542030

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 03 Oct 2020 15:26:49

Generated On: 10 Jun 2021 08:12:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542030

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 03 Oct 2020 15:26:49

Generated On: 10 Jun 2021 08:12:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542030

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 21 Oct 2020 18:29:42

Generated On: 10 Jun 2021 08:12:08

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542030

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 21 Oct 2020 18:29:42

Generated On: 10 Jun 2021 08:12:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542030

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 21 Oct 2020 18:29:42

Generated On: 10 Jun 2021 08:12:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542030

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 21 Oct 2020 18:29:42

Generated On: 10 Jun 2021 08:12:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542030

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Oct 2020 13:45:37

Generated On: 10 Jun 2021 08:12:08

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	22 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3542030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Oct 2020 13:45:48

Generated On: 10 Jun 2021 08:12:08

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	22 OCT 2020
Time of assessment (00:00-23:59)	09:15 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 09:15
Temperature (xxx.x)	98.0 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3542030

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Oct 2020 13:45:37

Generated On: 10 Jun 2021 08:12:08

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3542030

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Oct 2020 13:45:37

Generated On: 10 Jun 2021 08:12:08

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	22 OCT 2020
Collection time (00:00-23:59)	09:30 (24 HR)
Collection date and time (derived)	22 OCT 2020 09:30

US3542030

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Oct 2020 13:45:37

Generated On: 10 Jun 2021 08:12:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
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 ☐
Date and time of submission	20 OCT 2020 07:02:45
Patient Cloud Open Date & Time	20 OCT 2020 00:01
Patient Cloud Close Date & Time	24 OCT 2020 23:59

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 OCT 2020 09:12:16

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 NOV 2020 15:26:52
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 NOV 2020 15:02:23
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 NOV 2020 23:50:28

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 07:46:13
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 DEC 2020 12:12:24

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 DEC 2020 09:51:27
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 12:25:33

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 JAN 2021 13:18:11

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 JAN 2021 16:23:22

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 22:30:12

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 23:44:28

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 FEB 2021 12:00:42

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 FEB 2021 18:08:57

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 FEB 2021 13:14:19
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have 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):	
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 ☐
Date and time of submission	20 FEB 2021 08:23:48
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAR 2021 12:01:36
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have 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):	
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	07 MAR 2021 22:10:37
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 MAR 2021 18:17:54

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 09:17:15

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 MAR 2021 07:09:32

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 229

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 APR 2021 09:07:19
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 APR 2021 09:17:29

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have 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):	
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	26 APR 2021 12:00:43
Patient Cloud Open Date & Time	24 APR 2021 00:01
Patient Cloud Close Date & Time	28 APR 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 08:59:33

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

Date and time of submission	
Patient Cloud Open Date & Time	25 SEP 2021 00:01
Patient Cloud Close Date & Time	29 SEP 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

Date and time of submission	
Patient Cloud Open Date & Time	05 FEB 2022 00:01
Patient Cloud Close Date & Time	09 FEB 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 551

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

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

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

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

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

Fever (Temperature $\geq$ 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

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06 APR 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

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13 APR 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

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20 APR 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 621

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

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06 JUL 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

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20 JUL 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 705

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

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27 JUL 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

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03 AUG 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 719

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 726

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 733

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

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24 AUG 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 754

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 775

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

DAY 782

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3542030

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:12:08

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		01 MAR 2021 12:00:59

US3542030

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 20 Nov 2020 04:10:05

Generated On: 10 Jun 2021 08:12:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542030

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 20 Nov 2020 04:10:05

Generated On: 10 Jun 2021 08:12:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542030

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 27 Dec 2020 22:57:30

Generated On: 10 Jun 2021 08:12:08

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

US3542030

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 27 Dec 2020 22:57:30

Generated On: 10 Jun 2021 08:12:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542030

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 22 Jan 2021 18:10:03

Generated On: 10 Jun 2021 08:12:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542030

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 22 Jan 2021 18:10:03

Generated On: 10 Jun 2021 08:12:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542030

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 20:11:07

Generated On: 10 Jun 2021 08:12:08

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

US3542030

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:11:07

Generated On: 10 Jun 2021 08:12:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542030

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 16:51:18

Generated On: 10 Jun 2021 08:12:08

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	25 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT4

US3542030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 21:12:57

Generated On: 10 Jun 2021 08:12:08

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3542030

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 16:51:18

Generated On: 10 Jun 2021 08:12:08

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3542030

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 16:51:18

Generated On: 10 Jun 2021 08:12:08

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 MAR 2021

Collection time (00:00-23:59)

09:29 (24 HR)

Collection date and time (derived)

25 MAR 2021 09:29

US3542030

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 16:51:18

Generated On: 10 Jun 2021 08:12:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542030

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542030

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 10 Dec 2020 16:07:55

Generated On: 10 Jun 2021 08:12:08

Date of Contact	08 DEC 2020
Time of Contact	08:45
Date and Time of Contact (derived)	08 DEC 2020 08:45
Type of Contact	Clinic Visit - Scheduled☐ Clinical Visit - Unscheduled☐ Safety Call☒ Convalescent Tele-visit☐
Has the subject reported symptoms of SARS-COV-2?	Yes☒ No☐

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Jan 2021 02:40:10

Generated On: 10 Jun 2021 08:12:08

Symptom Day

Day 1	☒
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Jan 2021 02:40:10

Generated On: 10 Jun 2021 08:12:08

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	07 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐

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EAB) (1725)

327 of 3457

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Jan 2021 02:40:10

Generated On: 10 Jun 2021 08:12:08

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Jan 2021 02:40:10

Generated On: 10 Jun 2021 08:12:08

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Jan 2021 02:40:10

Generated On: 10 Jun 2021 08:12:08

Symptom Day

Day 1	☐
Day 2	☒
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Jan 2021 02:40:10

Generated On: 10 Jun 2021 08:12:08

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	08 DEC 2020

Assessment Not Done	False

O2 Saturation	

O2 Saturation Units	

Temperature	

Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐

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EAB) (1725)

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US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Jan 2021 02:40:10

Generated On: 10 Jun 2021 08:12:08

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Jan 2021 02:40:10

Generated On: 10 Jun 2021 08:12:08

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Jan 2021 02:40:10

Generated On: 10 Jun 2021 08:12:08

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☒
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Jan 2021 02:40:10

Generated On: 10 Jun 2021 08:12:08

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	09 DEC 2020

Assessment Not Done	False

O2 Saturation	97 %

O2 Saturation Units	%

Temperature	98.4 F

Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐

Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Jan 2021 02:40:10

Generated On: 10 Jun 2021 08:12:08

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Jan 2021 02:40:10

Generated On: 10 Jun 2021 08:12:08

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 31 Jan 2021 19:17:01

Generated On: 10 Jun 2021 08:12:08

Date of Visit	09 DEC 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ☒ No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ☐ No ☒
Date of Test	09 DEC 2020
Type of Test Performed	Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☐ No ☒
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes ☐ No ☐
COVID-19 Positive (CSA Programming Field Only)	0

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 10 Dec 2020 16:07:55

Generated On: 10 Jun 2021 08:12:08

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 31 Jan 2021 19:17:01

Generated On: 10 Jun 2021 08:12:08

Date of Contact	08 DEC 2020
Time of Contact	08:45
Date and Time of Contact (derived)	08 DEC 2020 08:45
Type of Contact	Clinic Visit - Scheduled☐ Clinical Visit - Unscheduled☐ Safety Call☒ Convalescent Tele-visit☐
Has the subject reported symptoms of SARS-COV-2?	Yes☒ No☐

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 31 Jan 2021 19:17:01

Generated On: 10 Jun 2021 08:12:08

Date of Visit 09 DEC 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☐ No ☒

Date of Test 09 DEC 2020

Type of Test Performed Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☒ No ☐

If yes, provide lab information below

Lab/ Institution Test Performed GEORGE WASHINGTON UNIVERSITY HOSPITAL LAB

CLIA Certified? Yes ☒ No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: COVID-19 Contact

Data signed: (b) (4) 10 Mar 2021 18:40:20

Generated On: 10 Jun 2021 08:12:08

Date of Contact	08 MAR 2021
Time of Contact	09:45
Date and Time of Contact (derived)	08 MAR 2021 09:45
Type of Contact	Clinic Visit - Scheduled☐ Clinical Visit - Unscheduled☐ Safety Call☒ Convalescent Tele-visit☐
Has the subject reported symptoms of SARS-COV-2?	Yes☒ No☐

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (1)

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

Symptom Day

Day 1	☒
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (1)

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	03 MAR 2021

Assessment Not Done	False

O2 Saturation	ND - Not Done

O2 Saturation Units	%

Temperature	ND - Not Done

Chills	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Cough	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Shortness of Breath	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Difficulty Breathing	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (1)

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

	Not Done	☐
Fatigue	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (1)

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (2)

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

Symptom Day

Day 1	☐
Day 2	☒
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (2)

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	04 MAR 2021

Assessment Not Done	False

O2 Saturation	ND - Not Done

O2 Saturation Units	%

Temperature	ND - Not Done

Chills	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Cough	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Shortness of Breath	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Difficulty Breathing	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (2)

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

	Not Done	☐
Fatigue	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (2)

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (3)

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☒
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (3)

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	05 MAR 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (3)

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

	Not Done	☐
Fatigue	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (3)

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (4)

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☒
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (4)

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	06 MAR 2021

Assessment Not Done	False

O2 Saturation	ND - Not Done

O2 Saturation Units	%

Temperature	ND - Not Done

Chills	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Cough	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Shortness of Breath	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Difficulty Breathing	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (4)

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

	Not Done	☐
Fatigue	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (4)

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (5)

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☒
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (5)

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	07 MAR 2021

Assessment Not Done	False

O2 Saturation	ND - Not Done

O2 Saturation Units	%

Temperature	ND - Not Done

Chills	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Cough	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Shortness of Breath	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Difficulty Breathing	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (5)

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

	Not Done	☐
Fatigue	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (5)

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (6)

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☒
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (6)

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	08 MAR 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (6)

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

	Not Done	☐
Fatigue	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (6)

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (7)

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☒
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (7)

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	09 MAR 2021

Assessment Not Done	False

O2 Saturation	ND - Not Done

O2 Saturation Units	%

Temperature	ND - Not Done

Chills	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Cough	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Shortness of Breath	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Difficulty Breathing	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (7)

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

	Not Done	☐
Fatigue	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (7)

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (8)

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☒
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (8)

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	10 MAR 2021

Assessment Not Done	False

O2 Saturation	97 %

O2 Saturation Units	%

Temperature	98.5 F

Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (8)

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

	Not Done	☐
Fatigue	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (8)

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 10 Mar 2021 22:22:30

Generated On: 10 Jun 2021 08:12:08

Date of Visit 10 MAR 2021

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☐ No ☒

Date of Test 10 MAR 2021

Type of Test Performed Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☒ No ☐

If yes, provide lab information below

Lab/ Institution Test Performed CLIA-CERTIFIED LAB OF DR. JEANNE JORDAN, GWU SCHOOL OF PUBLIC HEALTH

CLIA Certified? Yes ☒ No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3542030

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 10 Dec 2020 16:07:55

Generated On: 10 Jun 2021 08:12:08

Visit	Was Saliva Collected?	Date of Collection
Day 3	NA (COVID-19 Negative)	
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

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Folder: Illness Visit (2)

Form: Saliva Collection

Generated On: 10 Jun 2021 08:12:08

Visit	Was Saliva Collected?	Date of Collection
Day 3		
Day 5		
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

US3542030

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 10 Dec 2020 16:07:55

Generated On: 10 Jun 2021 08:12:08

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	09 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD1

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 10 Dec 2020 16:07:55

Generated On: 10 Jun 2021 08:12:08

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	09 DEC 2020
Time of assessment (00:00-23:59)	15:00 (24 HR)
Vital Signs Date and Time (derived)	09 DEC 2020 15:00
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.4 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 10 Dec 2020 16:07:55

Generated On: 10 Jun 2021 08:12:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 DEC 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3542030

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 10 Dec 2020 16:07:55

Generated On: 10 Jun 2021 08:12:08

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

09 DEC 2020

US3542030

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 10 Mar 2021 18:40:20

Generated On: 10 Jun 2021 08:12:08

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	10 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD1

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	10 MAR 2021
Time of assessment (00:00-23:59)	08:35 (24 HR)
Vital Signs Date and Time (derived)	10 MAR 2021 08:35
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.5 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3542030

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 MAR 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3542030

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

10 MAR 2021

US3542030

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

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 _____

US3542030

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Were vital signs assessed?	Yes ☐
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

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Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:08

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3542030

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 08:12:08

Was Blood Sample Taken for Immunologic Assessment of	Yes	☐
SARS_COV-2 Infection?	No	☐
	NA (COVID-19 Negative)	☐

Date of Collection	

US3542030

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

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 _____

US3542030

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Were vital signs assessed?	Yes ☐
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3542030

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:08

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3542030

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 08:12:08

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection _____

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 13 Jan 2021 03:41:03

Generated On: 10 Jun 2021 08:12:08

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	11 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	UNBLND_DECIDE

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 12 Mar 2021 22:38:41

Generated On: 10 Jun 2021 08:12:08

Date of updated informed consent (<i>dd MMM yyyy</i>)	11 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ☒ No ☐
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ☐ Amendment 6 or later ☒
Date of unblinding (<i>dd MMM yyyy</i>)	11 JAN 2021
Participant randomization assignment	mRNA-1273 ☐ Placebo ☒
Actual Dose 1	mRNA-1273 ☐ Placebo ☒ Not Administered ☐
Actual Dose 2	mRNA-1273 ☐ Placebo ☒ Not Administered ☐
Will participant receive mRNA-1273?	Yes ☒ No ☐
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Jan 2021 03:41:03

Generated On: 10 Jun 2021 08:12:08

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Jan 2021 03:41:03

Generated On: 10 Jun 2021 08:12:08

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	11 JAN 2021
Time of assessment (00:00-23:59)	13:46 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 13:46
Temperature (xxx.x)	97.5 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	105 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	95 mmHg
Diastolic Blood Pressure units	MMHG

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Jan 2021 03:41:03

Generated On: 10 Jun 2021 08:12:08

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	11 JAN 2021
Time of assessment (00:00-23:59)	14:26 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 14:26
Temperature (xxx.x)	98.4 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	98 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Jan 2021 03:41:03

Generated On: 10 Jun 2021 08:12:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 JAN 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Data signed: (b) (4) 13 Jan 2021 03:41:03

Generated On: 10 Jun 2021 08:12:08

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (<i>dd MMM yyyy</i>)	11 JAN 2021
Test performed	Urine ☒
	Serum ☐
Result	Positive ☐
	Negative ☒
Was FSH sample collected?	Yes ☐
	No ☒
Collection date	
Collection time	
Collection date and time (derived)	

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 13 Jan 2021 03:41:03

Generated On: 10 Jun 2021 08:12:08

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 11 JAN 2021

What was the treatment time? (00:00-23:59) 13:56 (24 HR)

Treatment Date and Time (derived) 11 JAN 2021 13:56

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

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Jan 2021 03:41:03

Generated On: 10 Jun 2021 08:12:08

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	11 JAN 2021
Collection time (00:00-23:59)	13:38 (24 HR)
Collection date and time (derived)	11 JAN 2021 13:38

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 13 Jan 2021 03:41:03

Generated On: 10 Jun 2021 08:12:08

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	11 JAN 2021
Collection time (00:00 - 23:59)	13:40
Collection Date and Time (derived)	11 JAN 2021 13:40

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 13 Jan 2021 03:41:03

Generated On: 10 Jun 2021 08:12:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542030

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 20:17:25

Generated On: 10 Jun 2021 08:12:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542030

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:59:56

Generated On: 10 Jun 2021 08:12:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

OLD29 Placebo Flag

1

US3542030

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 16:59:56

Generated On: 10 Jun 2021 08:12:08

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	08 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	OLD29

US3542030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 16:59:56

Generated On: 10 Jun 2021 08:12:08

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	08 FEB 2021
Time of assessment (00:00-23:59)	14:14 (24 HR)
Vital Signs Date and Time (derived)	08 FEB 2021 14:14
Temperature (xxx.x)	98.1 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3542030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 16:59:56

Generated On: 10 Jun 2021 08:12:08

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	08 FEB 2021
Time of assessment (00:00-23:59)	15:28 (24 HR)
Vital Signs Date and Time (derived)	08 FEB 2021 15:28
Temperature (xxx.x)	98 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3542030

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 16:59:56

Generated On: 10 Jun 2021 08:12:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 FEB 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3542030

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 16 Feb 2021 16:59:56

Generated On: 10 Jun 2021 08:12:08

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (<i>dd MMM yyyy</i>)	08 FEB 2021
Test performed	Urine ☒
	Serum ☐
Result	Positive ☐
	Negative ☒
Was FSH sample collected?	Yes ☐
	No ☒
Collection date	
Collection time	
Collection date and time (derived)	

US3542030

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 16:59:56

Generated On: 10 Jun 2021 08:12:08

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 08 FEB 2021

What was the treatment time? (00:00-23:59) 14:57 (24 HR)

Treatment Date and Time (derived) 08 FEB 2021 14:57

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3542030

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:59:56

Generated On: 10 Jun 2021 08:12:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542030

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 17:24:30

Generated On: 10 Jun 2021 08:12:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3542030

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:24:30

Generated On: 10 Jun 2021 08:12:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542030

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 04:08:31

Generated On: 10 Jun 2021 08:12:08

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	05 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	OLD57

US3542030

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Mar 2021 04:08:31

Generated On: 10 Jun 2021 08:12:08

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3542030

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 04:08:31

Generated On: 10 Jun 2021 08:12:08

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3542030

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 04:08:31

Generated On: 10 Jun 2021 08:12:08

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

05 MAR 2021

Collection time (00:00-23:59)

13:46 (24 HR)

Collection date and time (derived)

05 MAR 2021 13:46

US3542030

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 09 Sep 2020 01:41:06

Generated On: 10 Jun 2021 08:12:08

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3542030

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

AEID

Adverse event

INSECT BITES, BOTH LEGS

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)

27 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

29 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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EAB) (1725)

US3542030

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

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 Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3542030

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

AEID

Adverse event

GASTROENTERITIS

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)

04 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)

6 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3542030

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

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 Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

AEID	
Adverse event	CELLULITIS OF LEFT LEG
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)	29 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	07 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

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 Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3542030

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

AEID

Adverse event

TOOTH CROWN CRACKING

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)

01 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)

23 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

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	False
Concomitant Procedure	True
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 22:00:16

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AEID	
Adverse event	TOOTH 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)	19 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	19 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

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 Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

AEID	
Adverse event	PHARYNGITIS
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 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

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 Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

AEID	
Adverse event	TOOTH 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)	09 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	09 MAR 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	

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

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 Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

AEID	USA-US084-2021-MRNA-1273-P30 1000011
Adverse event	MORBID OBESITY
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)	22 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	22 APR 2021
Hospital Discharge Date (dd MMM yyyy)	23 APR 2021
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ 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	True
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	

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

PARTICIPANT WAS
HOSPITALIZED 22-23-APR-2021
FOR PLANNED SLEEVE
GASTRECTOMY FOR MORBID
OBESITY. PARTICIPANT ALSO
UNDERWENT HIATAL HERNIA
REPAIR (INCIDENTALLY
FOUND DURING SURGERY).

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

AEID	USA-US084-2021-MRNA-1273-P30 1000011
Adverse event	HIATAL HERNIA
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)	22 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	23 APR 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	True
Hospital Admission Date (dd MMM yyyy)	22 APR 2021
Hospital Discharge Date (dd MMM yyyy)	23 APR 2021
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐

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Form: Adverse Events (12)

Data signed: (b) (4) 28 Apr 2021 22:00:16

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ 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	False
Concomitant Procedure	True
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	

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

PARTICIPANT UNDERWENT
SLEEVE GASTRECTOMY ON
22-APR-2021 FOR MORBID
OBESITY. DURING SURGERY, A
HIATAL HERNIA WAS
INCIDENTALLY FOUND AND
REPAIRED. PARTICIPANT WAS
DISCHARGED ON 23-APR-2021.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 27 Aug 2020 15:36:35

Generated On: 10 Jun 2021 08:12:08

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication MILD ASTHMA

Dose per administration 400

Dose unit mg ☐
ug ☒
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

	Intramuscular	☐
	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1975	
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	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS

Dose per administration 1000

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 22:00:16

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☐
No ☒

Indication SUPPLEMENT

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☒
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK	1993
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	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1000

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☒
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication PANTAPROPAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

Dose per administration 20

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

EVERY MORNING

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2018
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	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication CELEBREX

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 200

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 22:00:16

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAR 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication CARDIOPROTECTIVE

Dose per administration 81

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUL 2018	
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	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication IMITREX

Prophylaxis Yes ☐
No ☒

Indication MIGRAINE HEADACHE

Dose per administration 25

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1998	
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	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication EXCEDRIN
[ACETAMINOPHEN/ASPIRIN/CA
FFEINE]

Prophylaxis Yes ☐
No ☒

Indication MIGRAINE HEADACHE

Dose per administration 2

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☒
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 1998	
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	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication ZYRTEC

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☒
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
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	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication FLONASE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify SPRAY

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☒
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
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	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS

Dose per administration 1.5

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

6-DAY TAPER

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 22:00:16

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	03 SEP 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	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication ONDANSETRON

Prophylaxis Yes ☐
No ☒

Indication GASTROENTERITIS
(ASSOCIATED NAUSEA)

Dose per administration 8

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 22:00:16

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	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	04 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	04 SEP 2020	
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	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication GASTROENTERITIS
(ASSOCIATED HEADACHE)

Dose per administration 1000

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		05 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		05 SEP 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	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication BENADRYL 2% CREAM

Prophylaxis Yes ☐
No ☒

Indication INSECT BITES

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify APPLICATION

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☒
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☒
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	28 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	28 AUG 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication BACTRIM DS

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS

Dose per administration 2

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☒
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		07 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication CORTISONE 1% CREAM

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify APPLICATION

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☒
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		03 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication CLINDAMYCIN

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR DENTAL
WORK

Dose per administration 600

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		23 SEP 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	☐

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication HYDROCODONE/ACETAMINOP
HEN

Prophylaxis Yes ☐
No ☒

Indication PAIN MANAGEMENT
SECONDARY TO DENTAL
WORK

Dose per administration 5/325

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

	Transdermal	☐
	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	27 SEP 2020	
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	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication PAIN MANAGEMENT
SECONDARY TO DENTAL
WORK

Dose per administration 1000

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	23 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	27 SEP 2020	
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	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☒
No ☐

Indication DENTAL WORK PROPHYLAXIS

Dose per administration 500

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		19 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	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication EXCEDRIN (250/250/65 MG)

Prophylaxis Yes ☐
No ☒

Indication TOOTH PAIN

Dose per administration 2

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☒
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		19 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	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication TOOTH PAIN

Dose per administration 650

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		19 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	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

	Intramuscular	☒
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		09 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	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication PHARYNGITIS

Dose per administration 650

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	07 MAR 2021	
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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication ACETAMINOPHEN/DIPHENHYD
RAMINE

Prophylaxis Yes ☐
No ☒

Indication PHARYNGITIS

Dose per administration 500/25

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

EVERY NIGHT AT BEDTIME AS
NEEDED

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		06 MAR 2021
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	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication TOOTH PAIN

Dose per administration 800

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	09 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		09 MAR 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	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication SLEEVE GASTRECTOMY

Dose per administration 975

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☒
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 APR 2021	
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)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication KETOROLAC

Prophylaxis Yes ☐
No ☒

Indication SLEEVE GASTRECTOMY

Dose per administration 15

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

EVERY 6 HOURS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	23 APR 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	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication METOCLOPRAMIDE

Prophylaxis Yes ☐
No ☒

Indication SLEEVE GASTRECTOMY

Dose per administration 10

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

EVERY 6 HOURS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	23 APR 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	☐

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication HYDROMORPHONE

Prophylaxis Yes ☐
No ☒

Indication SLEEVE GASTRECTOMY

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

EVERY 3 HOURS AS NEEDED

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	23 APR 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 ☐	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication ONDANSETRON

Prophylaxis Yes ☐
No ☒

Indication SLEEVE GASTRECTOMY

Dose per administration 4

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

EVERY 4 HOURS AS NEEDED

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	23 APR 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	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication CLINDAMYCIN

Prophylaxis Yes ☐
No ☒

Indication SLEEVE GASTRECTOMY

Dose per administration 900

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	22 APR 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	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication ENOXAPARIN (LOVENOX)

Prophylaxis Yes ☐
No ☒

Indication SLEEVE GASTRECTOMY

Dose per administration 40

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐
Intraocular ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 APR 2021	
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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication SLEEVE GASTRECTOMY

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 APR 2021	
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	☐

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication HYOSCYAMINE (LEVISON)

Prophylaxis Yes ☐
No ☒

Indication SLEEVE GASTRECTOMY

Dose per administration 0.125

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 APR 2021	
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	☐

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication SLEEVE GASTRECTOMY

Dose per administration 300

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 APR 2021	
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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3542030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 20 Nov 2020 04:10:05

Generated On: 10 Jun 2021 08:12:08

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3542030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 28 Apr 2021 22:00:16

Generated On: 10 Jun 2021 08:12:08

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
23 SEP 2020	TOOTH CROWN REPLACEMENT	Adverse Event	
28 SEP 2020	DENTAL FILLING REPLACEMENT	Medical History	
19 OCT 2020	TOOTH CROWN REPAIR	Adverse Event	
17 FEB 2021	UPPER ENDOSCOPY	Diagnostic	
09 MAR 2021	ROOT CANAL	Medical History	
22 APR 2021	SLEEVE GASTRECTOMY	Other	SAE (MORBID OBESITY)
22 APR 2021	HIATAL HERNIA REPAIR	Other	SAE (HIATAL HERNIA)

US3542030

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:12:08

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3542030

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:12:08

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3542030

Folder: SAE USA-US084-2021-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 22:00:17

Generated On: 10 Jun 2021 08:12:08

SAEID	USA-US084-2021-MRNA-1273-P301000011
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3542030

Folder: SAE USA-US084-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 22:00:17

Generated On: 10 Jun 2021 08:12:08

SAEID	USA-US084-2021-MRNA-1273-P301000011
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	27/APR/2021 14:17
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3542030 (Prod: George Washington University)

US3542030

Form: Participant Creation

Generated On: 10 Jun 2021 08:12:08

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:50:29
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'US3542030'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 15:40:46

US3542030

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	(b) (4) Elissa Malkin (b) (4)	20 Aug 2020 16:27:22

US3542030

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '20 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 15:40:47

US3542030

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Clinic (Clinic)'	(b) (4) Elissa Malkin (b) (4)	20 Aug 2020 16:27:22

US3542030

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'SCRN'	System	20 Aug 2020 16:27:22

US3542030

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:08

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered (b) (6) 1963'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 15:40:48

US3542030

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:08

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '56'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:49:45

US3542030

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:08

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'YEARS'	System	21 Aug 2020 17:49:45

US3542030

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:08

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered '56'	System	20 Aug 2020 16:27:37

US3542030

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:08

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Female (F)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:49:45

US3542030

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:08

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:49:45

US3542030

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:08

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'l'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:49:45

US3542030

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:08

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:49:45

US3542030

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:08

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:49:45
	(b) (4)	

US3542030

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:08

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:49:45

US3542030

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:08

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:49:45

US3542030

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:08

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:49:45

US3542030

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:08

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:49:45
	(b) (4)	

US3542030

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:08

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:49:45

US3542030

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:08

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:49:45

US3542030

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:12:08

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '20 Aug 2020'	(b) (4) Elissa Malkin (b) (4) (b) (4)	20 Aug 2020 16:27:37

US3542030

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:12:08

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'Aug 2020'	System	20 Aug 2020 16:27:37

US3542030

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:12:08

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered '2020'	System	20 Aug 2020 16:27:37

US3542030

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:12:08

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Amendment 2 (2)'	(b) (4) Elissa Malkin (b) (4)	20 Aug 2020 16:27:37

US3542030

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:12:08

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	(b) (4) Elissa Malkin (b) (4)	20 Aug 2020 16:27:37

US3542030

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:12:08

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Elissa Malkin (b) (4) (b) (4)	20 Aug 2020 16:27:37

US3542030

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:12:08

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Elissa Malkin (b) (4) (b) (4)	20 Aug 2020 16:27:37

US3542030

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:12:08

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Elissa Malkin (b) (4)	20 Aug 2020 16:27:37

US3542030

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:12:08

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 15:40:47

US3542030

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:12:08

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'I'	System	20 Aug 2020 17:08:20

US3542030

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:12:08

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	(b) (4) Elissa Malkin (b) (4)	20 Aug 2020 17:08:20

US3542030

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:12:08

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:15:02

US3542030

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:12:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4)	21 Aug 2020 18:17:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Aug 2020 18:17:52
Data point term sent to Coder	System	21 Aug 2020 18:16:22
User entered 'Mild intermittent asthma'	Taylor Ladson (b) (4)	21 Aug 2020 18:15:31

US3542030

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:12:08

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'un UNK 1975'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:15:31

US3542030

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:15:31

US3542030

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:12:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:15:31

US3542030

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:12:08

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:15:31
	(b) (4)	

US3542030

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:12:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:15:31

US3542030

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:12:08

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'Jan 1975'	System	21 Aug 2020 18:15:31

US3542030

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:12:08

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered '1975'	System	21 Aug 2020 18:15:31

US3542030

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:12:08

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered empty.	System	21 Aug 2020 18:15:31

US3542030

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:12:08

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered empty.	System	21 Aug 2020 18:15:31

US3542030

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:12:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Diabetes mellitus, LLT: Diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 18:17:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 18:17:15
Data point term sent to Coder	System	21 Aug 2020 18:16:22
User entered 'Diabetes mellitus'	Taylor Ladson (b) (4)	21 Aug 2020 18:15:45

US3542030

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:12:08

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'UN UNK 2005' reason for change:	(b) (4)	
Data Entry Error	Hannah Yellin (b) (4)	25 Aug 2020 19:53:05
User entered 'un UNK 2015'	(b) (4)	
	Taylor Ladson (b) (4)	21 Aug 2020 18:15:45
	(b) (4)	

US3542030

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:15:45

US3542030

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:12:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:15:45

US3542030

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:12:08

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:15:45

US3542030

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:12:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:15:45

US3542030

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:12:08

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'Jan 2005'	System	25 Aug 2020 19:53:05
User entered 'Jan 2015'	System	21 Aug 2020 18:15:45

US3542030

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:12:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered '2005'	System	25 Aug 2020 19:53:05
User entered '2015'	System	21 Aug 2020 18:15:45

US3542030

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:12:08

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered empty.	System	21 Aug 2020 18:15:45

US3542030

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:12:08

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered empty.	System	21 Aug 2020 18:15:45

US3542030

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:12:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:27:04
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\23.0.	Coder Import (b) (4)	31 Aug 2020 15:59:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	31 Aug 2020 15:59:37
Data point term sent to Coder	System	31 Aug 2020 15:58:51
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\23.0.	Coder Import (b) (4)	31 Aug 2020 15:58:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	31 Aug 2020 15:58:40
User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	System	31 Aug 2020 15:58:07
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' answered with 'Separate event reported for common bile duct stent and repair per query resolution' (Site from System).	Hannah Yellin (b) (4)	31 Aug 2020 15:58:07
Data point term sent to Coder	System	31 Aug 2020 15:57:46
Signature has been broken.	Hannah Yellin (b) (4)	31 Aug 2020 15:57:11
User entered 'CHOLECYSTECTOMY' reason for change: Per Query Resolution	Hannah Yellin (b) (4)	31 Aug 2020 15:57:11
User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	Coder Import (b) (4)	31 Aug 2020 14:28:28
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
Data point term sent to Coder	System	25 Aug 2020 19:54:06
Coding entries removed.	Hannah Yellin (b) (4)	25 Aug 2020 19:53:42

US3542030

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:12:08

[Condition](#)

Audit	User	Time (GMT)
User entered 'CHOLECYSTECTOMY with common bile duct stent and repair' reason for change: Data Entry Error	Hannah Yellin (b) (4)	25 Aug 2020 19:53:42
User coded data point as SOC: Surgical and medical procedures, HLG: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 18:17:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 18:17:16
Data point term sent to Coder	System	21 Aug 2020 18:16:25
User entered 'Cholecystectomy'	Taylor Ladson (b) (4)	21 Aug 2020 18:16:13

US3542030

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:12:08

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'un May 1996'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:16:13

US3542030

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:16:13

US3542030

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:12:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:16:13

US3542030

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:12:08

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	(b) (4)	
	System	21 Aug 2020 18:17:19
User entered 'UN May 1996' reason for change: Per Query Resolution	Taylor Ladson (b) (4)	21 Aug 2020 18:17:19
	(b) (4)	
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	21 Aug 2020 18:16:13
User entered 'un UNK 1996'	Taylor Ladson (b) (4)	21 Aug 2020 18:16:13
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:12:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:16:13

US3542030

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:12:08

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'May 1996'	System	21 Aug 2020 18:16:13

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:12:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered '1996'	System	21 Aug 2020 18:16:13

US3542030

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:12:08

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'May 1996'	System	21 Aug 2020 18:17:19
User entered 'Jan 1996'	System	21 Aug 2020 18:16:13

US3542030

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:12:08

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered '1996'	System	21 Aug 2020 18:16:13

US3542030

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:12:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	21 Aug 2020 18:19:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 18:19:22
Data point term sent to Coder	System	21 Aug 2020 18:18:31
User entered 'Gastroesophageal reflux disease'	Taylor Ladson (b) (4)	21 Aug 2020 18:17:50
	(b) (4)	

US3542030

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:12:08

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'un UNK 2018'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:17:50

US3542030

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:17:50

US3542030

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:12:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:17:50

US3542030

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:12:08

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:17:50

US3542030

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:12:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:17:50

US3542030

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:12:08

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'Jan 2018'	System	21 Aug 2020 18:17:50

US3542030

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:12:08

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered '2018'	System	21 Aug 2020 18:17:50

US3542030

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:12:08

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered empty.	System	21 Aug 2020 18:17:50

US3542030

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:12:08

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered empty.	System	21 Aug 2020 18:17:50

US3542030

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:12:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:27:04
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Bile duct stent insertion, LLT: Bile duct stent insertion - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 17:47:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 17:47:49
Data point term sent to Coder	System	31 Aug 2020 15:57:47
User entered 'COMMON BILE DUCT STENT AND REPAIR'	Hannah Yellin (b) (4)	31 Aug 2020 15:57:35

US3542030

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:12:08

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:27:04
User entered 'un May 1996'	(b) (4) Hannah Yellin (b) (4)	31 Aug 2020 15:57:35
	(b) (4)	

US3542030

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:27:04
User entered '0'	(b) (4) Hannah Yellin (b) (4)	31 Aug 2020 15:57:35
	(b) (4)	

US3542030

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:12:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:27:04
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	31 Aug 2020 15:57:35
	(b) (4)	

US3542030

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:12:08

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:27:04
User entered 'un May 1996'	(b) (4) Hannah Yellin (b) (4)	31 Aug 2020 15:57:35
	(b) (4)	

US3542030

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:12:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:27:04
User entered '0'	(b) (4) Hannah Yellin (b) (4)	31 Aug 2020 15:57:35
	(b) (4)	

US3542030

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:12:08

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'May 1996'	System	31 Aug 2020 15:57:35

US3542030

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:12:08

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered '1996'	System	31 Aug 2020 15:57:35

US3542030

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:12:08

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'May 1996'	System	31 Aug 2020 15:57:35

US3542030

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:12:08

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered '1996'	System	31 Aug 2020 15:57:35

US3542030

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:12:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee replacement - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 13:34:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 13:34:46
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. '(Site from DM).	(b) (4), (b) (6)	09 Oct 2020 10:34:15
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
Data point term sent to Coder	System (b) (4)	07 Oct 2020 22:24:28
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'Updated.' (Site from DM).	David Diemert (b) (4)	07 Oct 2020 22:23:41
Coding entries removed.	David Diemert (b) (4)	07 Oct 2020 22:23:35
Signature has been broken.	David Diemert (b) (4)	07 Oct 2020 22:23:35
User entered 'LEFT KNEE REPLACEMENT due to osteoarthritis' reason for change: New Information	David Diemert (b) (4)	07 Oct 2020 22:23:35
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. '(Site from DM).	(b) (4), (b) (6)	30 Sep 2020 13:41:41
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee replacement - version MedDRA\23.0.	Coder Import (b) (4)	21 Aug 2020 18:19:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Aug 2020 18:19:22

US3542030

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:12:08

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	21 Aug 2020 18:18:32
User entered 'Left knee replacement'	Taylor Ladson (b) (4)	21 Aug 2020 18:18:19
	(b) (4)	

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Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:12:08

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'un Oct 2019'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:18:19

US3542030

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:18:19

US3542030

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:12:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:18:19

US3542030

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:12:08

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'un Oct 2019'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:18:19

US3542030

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:12:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:18:19

US3542030

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:12:08

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'Oct 2019'	System	21 Aug 2020 18:18:19

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Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:12:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered '2019'	System	21 Aug 2020 18:18:19

US3542030

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:12:08

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'Oct 2019'	System	21 Aug 2020 18:18:19

US3542030

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:12:08

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered '2019'	System	21 Aug 2020 18:18:19

US3542030

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:12:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthritis, PT: Osteoarthritis, LLT: Osteoarthritis knees - version MedDRA\23.0.	Coder Import (b) (4)	07 Oct 2020 23:40:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	07 Oct 2020 23:40:58
Data point term sent to Coder	System	07 Oct 2020 22:24:30
Coding entries removed.	David Diemert (b) (4)	07 Oct 2020 22:24:28
Signature has been broken.	David Diemert (b) (4)	07 Oct 2020 22:24:28
User entered 'OsteoARTHRITIS of knees' reason for change: Data Entry Error	David Diemert (b) (4)	07 Oct 2020 22:24:28
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Knee arthritis - version MedDRA\23.0.	Coder Import (b) (4)	25 Aug 2020 19:55:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Aug 2020 19:55:33
Data point term sent to Coder	System	25 Aug 2020 19:55:09
Coding entries removed.	Hannah Yellin (b) (4)	25 Aug 2020 19:55:04
User entered 'RIGHT knee ARTHRITIS' reason for change: Data Entry Error	Hannah Yellin (b) (4)	25 Aug 2020 19:55:04
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Arthritis - version MedDRA\23.0.	Coder Import (b) (4)	22 Aug 2020 05:18:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	22 Aug 2020 05:18:24
Data point term sent to Coder	System	21 Aug 2020 18:19:33
User entered 'right arthritis'	Taylor Ladson (b) (4)	21 Aug 2020 18:18:40

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Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:12:08

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'un UNK 2010'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:18:40

US3542030

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:18:40

US3542030

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:12:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:18:40

US3542030

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:12:08

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:18:40
	(b) (4)	

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Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:12:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:18:40

US3542030

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:12:08

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'Jan 2010'	System	21 Aug 2020 18:18:40

US3542030

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:12:08

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered '2010'	System	21 Aug 2020 18:18:40

US3542030

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:12:08

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered empty.	System	21 Aug 2020 18:18:40

US3542030

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:12:08

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered empty.	System	21 Aug 2020 18:18:40

US3542030

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:12:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Renal calculi - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 18:20:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 18:20:17
Data point term sent to Coder	System	21 Aug 2020 18:19:35
User entered 'Renal calculi'	Taylor Ladson (b) (4)	21 Aug 2020 18:19:02

US3542030

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:12:08

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '23 Jul 2020'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:19:02

US3542030

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:19:02

US3542030

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:12:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:19:02

US3542030

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:12:08

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '23 Jul 2020'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:19:02

US3542030

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:12:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:19:02

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Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:12:08

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'Jul 2020'	System	21 Aug 2020 18:19:02

US3542030

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:12:08

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered '2020'	System	21 Aug 2020 18:19:02

US3542030

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:12:08

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'Jul 2020'	System	21 Aug 2020 18:19:02

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Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:12:08

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered '2020'	System	21 Aug 2020 18:19:02

US3542030

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:12:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine headache - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 18:14:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 18:14:39
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
Data point term sent to Coder	System (b) (4)	25 Aug 2020 19:56:10
Coding entries removed.	Hannah Yellin (b) (4)	25 Aug 2020 19:55:35
User entered 'INFREQUENT MIGRAINE headache' reason for change: Data Entry Error	Hannah Yellin (b) (4)	25 Aug 2020 19:55:35
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\23.0.	Coder Import (b) (4)	21 Aug 2020 18:21:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Aug 2020 18:21:20
Data point term sent to Coder	System	21 Aug 2020 18:20:37
User entered 'Infrequent Migraines'	Taylor Ladson (b) (4)	21 Aug 2020 18:19:48

US3542030

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:12:08

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'un UNK 1998'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:19:48

US3542030

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:19:48

US3542030

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:12:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:19:48

US3542030

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:12:08

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:19:48

US3542030

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:12:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:19:48

US3542030

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:12:08

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'Jan 1998'	System	21 Aug 2020 18:19:48

US3542030

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:12:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered '1998'	System	21 Aug 2020 18:19:48

US3542030

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:12:08

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered empty.	System	21 Aug 2020 18:19:48

US3542030

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:12:08

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered empty.	System	21 Aug 2020 18:19:48

US3542030

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:12:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 18:21:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 18:21:38
Data point term sent to Coder	System	21 Aug 2020 18:20:37
User entered 'Seasonal allergies'	Taylor Ladson (b) (4)	21 Aug 2020 18:20:01

US3542030

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:12:08

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'un UNK 1968'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:20:01

US3542030

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:20:01

US3542030

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:12:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:20:01

US3542030

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:12:08

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:20:01

US3542030

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:12:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:20:01

US3542030

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:12:08

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'Jan 1968'	System	21 Aug 2020 18:20:01

US3542030

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:12:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered '1968'	System	21 Aug 2020 18:20:01

US3542030

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:12:08

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered empty.	System	21 Aug 2020 18:20:01

US3542030

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:12:08

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered empty.	System	21 Aug 2020 18:20:01

US3542030

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:12:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:57:30
User coded data point as SOC: Gastrointestinal disorders, HLGT: Dental and gingival conditions, HLT: Dental and periodontal infections and inflammations, PT: Dental caries, LLT: Dental caries - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	18 Dec 2020 16:19:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Dec 2020 16:19:08
Data point term sent to Coder	System	18 Dec 2020 16:17:03
User entered 'Dental caries'	Erika Faust (b) (4)	18 Dec 2020 16:16:49
	(b) (4)	

US3542030

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:12:08

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:57:30
User entered empty.	(b) (4) Erika Faust (b) (4)	18 Dec 2020 16:16:49

US3542030

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:57:30
User entered 'l'	(b) (4) Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:16:49

US3542030

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:12:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:57:30
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	(b) (4) System	18 Dec 2020 20:24:19
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	18 Dec 2020 16:16:49
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:16:49

US3542030

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:12:08

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:57:30
User entered empty; reason for change Per Query Resolution	(b) (4) Elissa Malkin (b) (4)	18 Dec 2020 20:24:19
User entered '28 Sep 2020'	(b) (4) Erika Faust (b) (4)	18 Dec 2020 16:16:49

US3542030

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:12:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:57:30
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:16:49

US3542030

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:12:08

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered empty.	System	18 Dec 2020 16:16:49

US3542030

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:12:08

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered empty.	System	18 Dec 2020 16:16:49

US3542030

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:12:08

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered empty.	System	18 Dec 2020 20:24:19
User entered 'Sep 2020'	System	18 Dec 2020 16:16:49

US3542030

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:12:08

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered empty.	System	18 Dec 2020 20:24:19
User entered '2020'	System	18 Dec 2020 16:16:49

US3542030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:51:36

US3542030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '20 Aug 2020'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:51:36

US3542030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '11:57'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:51:36

US3542030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered '20 Aug 2020 11:57'	System	21 Aug 2020 17:51:36

US3542030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '65' in	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:51:36
DataPoint set to visible.	(b) (4) System	20 Aug 2020 17:08:20

US3542030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '289' lb	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:51:36
DataPoint set to visible.	(b) (4) System	20 Aug 2020 17:08:20

US3542030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
Amendment Manager: User entered '48.19267'	System	17 Sep 2020 00:16:05
User entered '48.2'	System	21 Aug 2020 17:51:36
DataPoint set to visible.	System	20 Aug 2020 17:08:20

US3542030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'kg/m2'	System	21 Aug 2020 17:51:36
DataPoint set to visible.	System	20 Aug 2020 17:08:20

US3542030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:51:36

US3542030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:51:36
	(b) (4)	

US3542030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:51:36
	(b) (4)	

US3542030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:51:36

US3542030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'bpm'	System	21 Aug 2020 17:51:36

US3542030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:51:36

US3542030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'breaths/min'	System	21 Aug 2020 17:51:36

US3542030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:51:36

US3542030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'mmHg'	System	21 Aug 2020 17:51:36

US3542030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:51:36

US3542030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'mmHg'	System	21 Aug 2020 17:51:36

US3542030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15

US3542030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15

US3542030

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Dec 2020 19:24:50
Signature has been broken.	(b) (4)	
	DeEnna Wedding (b) (4)	11 Dec 2020 19:40:47
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	DeEnna Wedding (b) (4)	11 Dec 2020 19:40:47
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
	(b) (4)	
User entered 'No (N)'	Taylor Ladson (b) (4)	21 Aug 2020 17:51:51
	(b) (4)	

US3542030

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Dec 2020 19:24:50
Signature has been broken.	(b) (4)	
	DeEnna Wedding (b) (4)	11 Dec 2020 19:40:47
	(b) (4)	
User entered '20 Aug 2020' reason for change: Data Entry Error	DeEnna Wedding (b) (4)	11 Dec 2020 19:40:47
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	27 Aug 2020 15:36:36
	(b) (4)	
User entered empty.	Taylor Ladson (b) (4)	21 Aug 2020 17:51:51
	(b) (4)	

US3542030

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:12:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '20 Aug 2020'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:52:54

US3542030

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:12:08

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:52:54

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:12:08

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:52:54
	(b) (4)	

US3542030

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:12:08

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:52:54

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:12:08

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:52:54

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:12:08

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:52:54

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:12:08

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:52:54
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:12:08

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:52:54

US3542030

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:53:48

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Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '20 Aug 2020'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:53:48

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Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Urine (URINE)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:53:48

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Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Negative (NEGATIVE)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:53:48

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Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:53:48

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Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:53:48
	(b) (4)	

US3542030

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:53:48
	(b) (4)	

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Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered empty.	System	21 Aug 2020 17:53:48

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:08

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:54:22

US3542030

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:08

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:54:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:08

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:54:22

US3542030

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:08

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:54:22

US3542030

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:08

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:54:22

US3542030

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:08

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:54:22

US3542030

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:08

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	21 Aug 2020 17:54:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 17:54:31
User entered 'No (N)' reason for change: Per Query Resolution	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:54:31
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 17:54:22
User entered empty.	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:54:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:08

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:54:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:08

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:54:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:08

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:54:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:08

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:54:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:08

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:54:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:08

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Office administrator'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:54:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:08

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:54:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:08

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:54:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:08

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:54:22
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:08

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:54:22
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:08

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:54:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:08

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'l'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:54:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:08

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:54:22

US3542030

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:08

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:54:22
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	Elissa Malkin (b) (4) (b) (4)	20 Aug 2020 17:07:51

US3542030

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	27 Aug 2020 15:36:36
User entered '20 Aug 2020'	(b) (4)	
	Elissa Malkin (b) (4)	20 Aug 2020 17:07:51
	(b) (4)	

US3542030

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	27 Aug 2020 15:36:36
User entered 'Clinic (Clinic)'	(b) (4) Elissa Malkin (b) (4) (b) (4)	20 Aug 2020 17:07:51

US3542030

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered 'VISIT1'	System	20 Aug 2020 17:07:51

US3542030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:12:08

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	27 Aug 2020 15:36:36
User entered '20 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 16:15:05

US3542030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:12:08

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	27 Aug 2020 15:36:36
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:52:35
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:52:34
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 16:15:05
User entered '143744' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 16:15:05

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:12:08

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 16:15:05

US3542030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:12:08

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:54:51

US3542030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:12:08

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:54:51

US3542030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:12:08

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:54:51

US3542030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:12:08

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:54:51

US3542030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:12:08

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:54:51

US3542030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:12:08

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	29 Sep 2020 04:14:17
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	28 Sep 2020 19:35:41
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 10:36:56
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:44:47

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:08

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered missing code ND - Not Done.	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:57:24

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered missing code ND - Not Done.	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:57:24

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:08

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered missing code ND - Not Done.	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:57:24

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered missing code ND - Not Done.	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:57:24

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User accepted default value 'Pre-Dose (PREDOSE)'	Taylor Ladson (u) (4) (b) (4)	21 Aug 2020 17:57:24

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:57:24

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	27 Aug 2020 15:36:36
User entered '20 Aug 2020'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:57:24
	(b) (4)	

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered '11:57'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:57:24

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered '20 Aug 2020 11:57'	System	21 Aug 2020 17:57:24

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered '98' F	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:57:24

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered 'Oral (Oral)'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:57:24

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered empty.	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:57:24

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered '84'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:57:24

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered 'bpm'	System	21 Aug 2020 17:57:24

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered '16'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:57:24

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered 'breaths/min'	System	21 Aug 2020 17:57:24

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered '150'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:57:24

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered 'mmHg'	System	21 Aug 2020 17:57:24

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered '86'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:57:24

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered 'mmHg'	System	21 Aug 2020 17:57:24

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:08

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered missing code ND - Not Done.	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:57:24

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered missing code ND - Not Done.	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:57:24

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User accepted default value 'Post-Dose (POSTDOSE)'	Taylor Ladson (u) (4) (b) (4)	21 Aug 2020 17:57:52

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:57:52

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	27 Aug 2020 15:36:36
User entered '20 Aug 2020'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:57:52
	(b) (4)	

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered '13:36'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:57:52

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered '20 Aug 2020 13:36'	System	21 Aug 2020 17:57:52

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User closed query 'Temperature is not less than 38.0 C/100.4 F as required by protocol on day of first vaccination. Please confirm temperature is correct. (Exclusion criterion 4)' (Site from System).	System	21 Aug 2020 17:58:00
Query 'Temperature is not less than 38.0 C/100.4 F as required by protocol on day of first vaccination. Please confirm temperature is correct. (Exclusion criterion 4)' answered by data change (Site from System).	System	21 Aug 2020 17:58:00
User entered '98' F reason for change: Per Query Resolution	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:58:00
User opened query 'Temperature is not less than 38.0 C/100.4 F as required by protocol on day of first vaccination. Please confirm temperature is correct. (Exclusion criterion 4)' (Site from System).	System	21 Aug 2020 17:57:52
User entered '98' C	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:57:52

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered 'Oral (Oral)'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:57:52

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered empty.	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:57:52

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered '78'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:57:52

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered 'bpm'	System	21 Aug 2020 17:57:52

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered '16'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:57:52

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered 'breaths/min'	System	21 Aug 2020 17:57:52

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered '140'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:57:52

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered 'mmHg'	System	21 Aug 2020 17:57:52

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered '82'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:57:52

US3542030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered 'mmHg'	System	21 Aug 2020 17:57:52

US3542030

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	13 Dec 2020 19:24:50
Signature has been broken.	(b) (4)	
	DeEnna Wedding (b) (4)	11 Dec 2020 19:40:26
	(b) (4)	
User entered 'No (N)' reason for change: New Information	DeEnna Wedding (b) (4)	11 Dec 2020 19:40:26
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
	(b) (4)	
User entered 'Yes (Y)'	Taylor Ladson (b) (4)	21 Aug 2020 18:00:23
	(b) (4)	

US3542030

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	13 Dec 2020 19:24:50
Signature has been broken.	(b) (4)	
	DeEnna Wedding (b) (4)	11 Dec 2020 19:40:26
	(b) (4)	
User entered empty; reason for change New Information	DeEnna Wedding (b) (4)	11 Dec 2020 19:40:26
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
	(b) (4)	
User entered '20 Aug 2020'	Taylor Ladson (b) (4)	21 Aug 2020 18:00:23
	(b) (4)	

US3542030

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)' reason for change: Data Entry Error	Hannah Yellin (b) (4) (b) (4)	25 Aug 2020 20:01:41
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:58:31

US3542030

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered empty; reason for change Data Entry Error	Hannah Yellin (b) (4) (b) (4)	25 Aug 2020 20:01:41
User entered '20 Aug 2020'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:58:31

US3542030

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered empty; reason for change Data Entry Error	Hannah Yellin (b) (4) (b) (4)	25 Aug 2020 20:01:41
User entered 'Urine (URINE)'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:58:31

US3542030

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered empty; reason for change Data Entry Error	Hannah Yellin (b) (4) (b) (4)	25 Aug 2020 20:01:41
User entered 'Negative (NEGATIVE)'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:58:31

US3542030

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User closed query 'Per CDM: Please consider entering data as No. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 04:12:40
Query 'Per CDM: Please consider entering data as No. ' answered with 'Entered as No' (Site from DM).	Erika Faust (b) (4)	04 Dec 2020 14:45:41
Signature has been broken.	Erika Faust (b) (4)	04 Dec 2020 14:45:32
User entered 'No (N)' reason for change: Per Query Resolution	Erika Faust (b) (4)	04 Dec 2020 14:45:32
User opened query 'Per CDM: Please consider entering data as No. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 13:02:09
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty; reason for change Data Entry Error	Hannah Yellin (b) (4)	25 Aug 2020 20:01:41
User entered 'No (N)'	Taylor Ladson (b) (4)	21 Aug 2020 17:58:31

US3542030

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered empty.	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:58:31

US3542030

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered empty.	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:58:31

US3542030

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered empty.	System	21 Aug 2020 17:58:31

US3542030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	(b) (4) Elissa Malkin (b) (4) (b) (4)	20 Aug 2020 17:08:56

US3542030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered empty.	Elissa Malkin (b) (4) (b) (4)	20 Aug 2020 17:08:56

US3542030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered empty.	Elissa Malkin (b) (4) (b) (4)	20 Aug 2020 17:08:56

US3542030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered 'MRNA-1273 OR PLACEBO'	System	20 Aug 2020 17:08:56

US3542030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	27 Aug 2020 15:36:36
User entered '20 Aug 2020'	(b) (4) Elissa Malkin (b) (4)	20 Aug 2020 17:08:56

US3542030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	27 Aug 2020 15:36:36
User entered '13:06'	(b) (4) Elissa Malkin (b) (4)	20 Aug 2020 17:08:56

US3542030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered '20 Aug 2020 13:06'	System	20 Aug 2020 17:08:56

US3542030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	27 Aug 2020 15:36:36
User entered 'Left Arm (LEFT ARM)'	(b) (4) Elissa Malkin (b) (4) (b) (4)	20 Aug 2020 17:08:56

US3542030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered 'ONCE'	System	20 Aug 2020 17:08:56

US3542030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered 'INTRAMUSCULAR'	System	20 Aug 2020 17:08:56

US3542030

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 18:00:44

US3542030

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	27 Aug 2020 15:36:36
User entered '20 Aug 2020'	(b) (4)	
	Taylor Ladson (b) (4)	21 Aug 2020 18:00:44
	(b) (4)	

US3542030

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered '12:57'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 18:00:44

US3542030

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:08

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered '20 Aug 2020 12:57'	System	21 Aug 2020 18:00:44

US3542030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:12:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User closed query 'Per GCL Lab Reconciliation: Swab: Per PPD portal, swab sample was collected at Unscheduled visit on 04-AUG-2020 with accession number as "1F634079782" & at Visit 1 Day 1 on 20-AUG-2020 with accession number as "1F654888040"; however, per EDC, only one swab sample is present at Visit 1 Day 1 on 20-AUG-2020. Kindly confirm if two swab samples were collected, if collected at unscheduled visit, please update EDC as appropriate by initiating Covid-19 Assessment visit for 04-AUG-2020 and updating swab data in Covid Diagnostic Test eCRF as there is no provision on unscheduled visit to capture swab data, else clarify.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 07:57:01
Query 'Per GCL Lab Reconciliation: Swab: Per PPD portal, swab sample was collected at Unscheduled visit on 04-AUG-2020 with accession number as "1F634079782" & at Visit 1 Day 1 on 20-AUG-2020 with accession number as "1F654888040"; however, per EDC, only one swab sample is present at Visit 1 Day 1 on 20-AUG-2020. Kindly confirm if two swab samples were collected, if collected at unscheduled visit, please update EDC as appropriate by initiating Covid-19 Assessment visit for 04-AUG-2020 and updating swab data in Covid Diagnostic Test eCRF as there is no provision on unscheduled visit to capture swab data, else clarify.' answered with 'Per site processing lab, PPD GCL accessioned this sample. There was only one swab collected. This occurred at visit 1 on 20Aug2020.' (Site from DM).	Hannah Yellin (b) (4) (b) (4)	10 Feb 2021 19:50:17

US3542030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:12:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Swab: Per PPD portal, swab sample was collected at Unscheduled visit on 04-AUG-2020 with accession number as "1F634079782" & at Visit 1 Day 1 on 20-AUG-2020 with accession number as "1F654888040"; however, per EDC, only one swab sample is present at Visit 1 Day 1 on 20-AUG-2020. Kindly confirm if two swab samples were collected, if collected at unscheduled visit, please update EDC as appropriate by initiating Covid-19 Assessment visit for 04-AUG-2020 and updating swab data in Covid Diagnostic Test eCRF as there is no provision on unscheduled visit to capture swab data, else clarify.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 07:50:33
User closed query 'Per GCL Lab Reconciliation: Swab: Collection date recorded in GCL for Unscheduled visit is 04Aug2020 , however data is not yet entered in EDC. Please reconcile. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 10:02:57
Query 'Per GCL Lab Reconciliation: Swab: Collection date recorded in GCL for Unscheduled visit is 04Aug2020 , however data is not yet entered in EDC. Please reconcile. ' answered with 'Visit 1 was on 20Aug2020. Per site processing lab, this is correct in Preclarus. There was no visit on 04Aug2020.' (Site from DM).	Hannah Yellin (b) (4) (b) (4)	22 Jan 2021 18:32:52
User opened query 'Per GCL Lab Reconciliation: Swab: Collection date recorded in GCL for Unscheduled visit is 04Aug2020 , however data is not yet entered in EDC. Please reconcile. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 02:45:25
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:36:36
User entered '20 Aug 2020'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 18:01:02

US3542030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:12:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 18:01:02

US3542030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:12:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 18:01:02

US3542030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:12:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered '12:29'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 18:01:02

US3542030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:12:08

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered '20 Aug 2020 12:29'	System	21 Aug 2020 18:01:02

US3542030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:12:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Taylor Ladson (b) (4)	21 Aug 2020 18:01:02

US3542030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:12:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 18:01:02

US3542030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:12:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered empty.	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 18:01:02

US3542030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:12:08

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered empty.	System	21 Aug 2020 18:01:02

US3542030

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 18:01:06

US3542030

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered 'l'	System	21 Aug 2020 18:01:06

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	20 Aug 2020 17:08:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-20T13:46:20', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '01e558fe-bc46-44c9-b887-ee3c02b86657'	System	20 Aug 2020 17:46:43
User entered 'Yes (Y)'	System	20 Aug 2020 17:46:43

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-20T13:46:27', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '01e558fe-bc46-44c9-b887-ee3c02b86657'	System	20 Aug 2020 17:46:43
User entered '98.0'	System	20 Aug 2020 17:46:43

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-20T13:46:32', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '01e558fe-bc46-44c9-b887-ee3c02b86657'	System	20 Aug 2020 17:46:43
User entered 'No (N)'	System	20 Aug 2020 17:46:43

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-20T13:46:39', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '01e558fe-bc46-44c9-b887-ee3c02b86657' User entered '20 Aug 2020 13:46'	System	20 Aug 2020 17:46:43
	System	20 Aug 2020 17:46:43

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '20 Aug 2020 13:26'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '20 Aug 2020 15:56'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	20 Aug 2020 17:08:56
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '20 Aug 2020 16:51'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	20 Aug 2020 17:08:56
User entered 'Day 2'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-21T13:24:33', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '2ec19478-fed1-4858-bb93-2611f9378488' User entered 'Yes (Y)'	System	21 Aug 2020 17:24:52
	System	21 Aug 2020 17:24:52

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-21T13:24:40', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '2ec19478-fed1-4858-bb93-2611f9378488' User entered '98.1'	System	21 Aug 2020 17:24:52
	System	21 Aug 2020 17:24:52

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:08

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-21T13:24:44', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '2ec19478-fed1-4858-bb93-2611f9378488'	System	21 Aug 2020 17:24:52
User entered 'No (N)'	System	21 Aug 2020 17:24:52

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-21T13:24:49', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '2ec19478-fed1-4858-bb93-2611f9378488'	System	21 Aug 2020 17:24:52
User entered '21 Aug 2020 13:24'	System	21 Aug 2020 17:24:52

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	20 Aug 2020 17:08:56
User entered 'Day 3'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-22T15:37:49', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '86cba294-7c2a-477d-83ce-35007cf1020f' User entered 'Yes (Y)'	System	22 Aug 2020 19:38:07
	System	22 Aug 2020 19:38:07

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-22T15:37:56', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '86cba294-7c2a-477d-83ce-35007cf1020f' User entered '97.5'	System	22 Aug 2020 19:38:07
	System	22 Aug 2020 19:38:07

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:08

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-22T15:37:59', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '86cba294-7c2a-477d-83ce-35007cf1020f' User entered 'No (N)'	System	22 Aug 2020 19:38:07
	System	22 Aug 2020 19:38:07

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-22T15:38:03', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '86cba294-7c2a-477d-83ce-35007cf1020f' User entered '22 Aug 2020 15:38'	System	22 Aug 2020 19:38:07
	System	22 Aug 2020 19:38:07

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	20 Aug 2020 17:08:56
User entered 'Day 4'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-23T12:32:45', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'e2a09fd3-a1da-4628-a763-aabdf948a523' User entered 'Yes (Y)'	System	23 Aug 2020 16:34:43
	System	23 Aug 2020 16:34:43

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-23T12:34:35', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'e2a09fd3-a1da-4628-a763-aabdf948a523' User entered '98.4'	System	23 Aug 2020 16:34:43
	System	23 Aug 2020 16:34:43

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:08

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-23T12:34:38', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'e2a09fd3-a1da-4628-a763-aabdf948a523'	System	23 Aug 2020 16:34:43
User entered 'No (N)'	System	23 Aug 2020 16:34:43

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-23T12:34:41', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'e2a09fd3-a1da-4628-a763-aabdf948a523' User entered '23 Aug 2020 12:34'	System	23 Aug 2020 16:34:43
	System	23 Aug 2020 16:34:43

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	20 Aug 2020 17:08:56
User entered 'Day 5'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-24T13:10:43', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'ddfd4799-0edf-4e4e-8873-94013a4d4e83' User entered 'Yes (Y)'	System	24 Aug 2020 17:11:05
	System	24 Aug 2020 17:11:05

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-24T13:10:47', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'ddfd4799-0edf-4e4e-8873-94013a4d4e83' User entered '97.7'	System	24 Aug 2020 17:11:05
	System	24 Aug 2020 17:11:05

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:08

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-24T13:10:53', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'ddfd4799-0edf-4e4e-8873-94013a4d4e83'	System	24 Aug 2020 17:11:05
User entered 'No (N)'	System	24 Aug 2020 17:11:05

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-24T13:11:02', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'ddfd4799-0edf-4e4e-8873-94013a4d4e83' User entered '24 Aug 2020 13:11'	System	24 Aug 2020 17:11:05
	System	24 Aug 2020 17:11:05

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	20 Aug 2020 17:08:56
User entered 'Day 6'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-25T13:16:08', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '08518652-836a-4de9-9440-32103a8a66b9' User entered 'Yes (Y)'	System	25 Aug 2020 17:16:39
	System	25 Aug 2020 17:16:39

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-25T13:16:14', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '08518652-836a-4de9-9440-32103a8a66b9' User entered '98.0'	System	25 Aug 2020 17:16:39
	System	25 Aug 2020 17:16:39

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:08

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-25T13:16:19', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '08518652-836a-4de9-9440-32103a8a66b9'	System	25 Aug 2020 17:16:39
User entered 'No (N)'	System	25 Aug 2020 17:16:39

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-25T13:16:32', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '08518652-836a-4de9-9440-32103a8a66b9'	System	25 Aug 2020 17:16:39
User entered '25 Aug 2020 13:16'	System	25 Aug 2020 17:16:39

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	20 Aug 2020 17:08:56
User entered 'Day 7'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-26T16:35:08', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '8096e0e1-6195-4e5e-a25b-7e886ca474d3'	System	26 Aug 2020 20:35:38
User entered 'Yes (Y)'	System	26 Aug 2020 20:35:38

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-26T16:35:13', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '8096e0e1-6195-4e5e-a25b-7e886ca474d3' User entered '97.2'	System	26 Aug 2020 20:35:38
	System	26 Aug 2020 20:35:38

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:08

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-26T16:35:16', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '8096e0e1-6195-4e5e-a25b-7e886ca474d3'	System	26 Aug 2020 20:35:38
User entered 'No (N)'	System	26 Aug 2020 20:35:38

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-26T16:35:36', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '8096e0e1-6195-4e5e-a25b-7e886ca474d3'	System	26 Aug 2020 20:35:38
User entered '26 Aug 2020 16:35'	System	26 Aug 2020 20:35:38

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	20 Aug 2020 17:08:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-20T13:28:07', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '04c9f7fc-11a7-4cfe-baff-048675bd645d'	System	20 Aug 2020 17:28:51
User entered 'None (1)'	System	20 Aug 2020 17:28:51

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-20T13:28:28', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '04c9f7fc-11a7-4cfe-baff-048675bd645d' User entered 'No (N)'	System	20 Aug 2020 17:28:51
	System	20 Aug 2020 17:28:51

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-20T13:28:32', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '04c9f7fc-11a7-4cfe-baff-048675bd645d' User entered 'No (N)'	System	20 Aug 2020 17:28:51
	System	20 Aug 2020 17:28:51

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-20T13:28:45', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '04c9f7fc-11a7-4cfe-baff-048675bd645d' User entered 'None (1)'	System	20 Aug 2020 17:28:51
	System	20 Aug 2020 17:28:51

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-20T13:28:49', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '04c9f7fc-11a7-4cfe-baff-048675bd645d' User entered '20 Aug 2020 13:28'	System	20 Aug 2020 17:28:51
	System	20 Aug 2020 17:28:51

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '20 Aug 2020 13:26'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '20 Aug 2020 15:56'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	20 Aug 2020 17:08:56
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '20 Aug 2020 16:51'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	20 Aug 2020 17:08:56
User entered 'Day 2'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-21T13:18:30', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '6ae63b37-3712-465f-afe4-2bdf5b112533'	System	21 Aug 2020 17:19:55
User entered 'Does not interfere with activity (2)'	System	21 Aug 2020 17:19:55

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-21T13:18:40', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '6ae63b37-3712-465f-afe4-2bdf5b112533'	System	21 Aug 2020 17:19:55
User entered 'No (N)'	System	21 Aug 2020 17:19:55

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:08

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-21T13:19:05', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '6ae63b37-3712-465f-afe4-2bdf5b112533'	System	21 Aug 2020 17:19:55
User entered 'No (N)'	System	21 Aug 2020 17:19:55

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-21T13:19:17', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '6ae63b37-3712-465f-afe4-2bdf5b112533'	System	21 Aug 2020 17:19:55
User entered 'None (1)'	System	21 Aug 2020 17:19:55

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-21T13:19:53', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '6ae63b37-3712-465f-afe4-2bdf5b112533'	System	21 Aug 2020 17:19:55
User entered '21 Aug 2020 13:19'	System	21 Aug 2020 17:19:55

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	20 Aug 2020 17:08:56
User entered 'Day 3'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-22T15:38:20', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '9428f04b-a2ad-4c94-bfda-031ba246e070'	System	22 Aug 2020 19:38:47
User entered 'Does not interfere with activity (2)'	System	22 Aug 2020 19:38:47

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-22T15:38:26', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '9428f04b-a2ad-4c94-bfda-031ba246e070' User entered 'No (N)'	System	22 Aug 2020 19:38:47
	System	22 Aug 2020 19:38:47

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:08

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-22T15:38:29', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '9428f04b-a2ad-4c94-bfda-031ba246e070' User entered 'No (N)'	System	22 Aug 2020 19:38:47
	System	22 Aug 2020 19:38:47

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-22T15:38:39', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '9428f04b-a2ad-4c94-bfda-031ba246e070' User entered 'None (1)'	System	22 Aug 2020 19:38:47
	System	22 Aug 2020 19:38:47

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-22T15:38:43', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '9428f04b-a2ad-4c94-bfda-031ba246e070' User entered '22 Aug 2020 15:38'	System	22 Aug 2020 19:38:47
	System	22 Aug 2020 19:38:47

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	20 Aug 2020 17:08:56
User entered 'Day 4'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-23T12:32:11', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'dd174a8a-2586-44aa-9a36-48a609ec9cc4'	System	23 Aug 2020 16:32:37
User entered 'None (1)'	System	23 Aug 2020 16:32:37

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-23T12:32:14', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'dd174a8a-2586-44aa-9a36-48a609ec9cc4'	System	23 Aug 2020 16:32:37
User entered 'No (N)'	System	23 Aug 2020 16:32:37

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:08

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-23T12:32:23', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'dd174a8a-2586-44aa-9a36-48a609ec9cc4'	System	23 Aug 2020 16:32:37
User entered 'No (N)'	System	23 Aug 2020 16:32:37

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-23T12:32:33', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'dd174a8a-2586-44aa-9a36-48a609ec9cc4'	System	23 Aug 2020 16:32:37
User entered 'None (1)'	System	23 Aug 2020 16:32:37

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-23T12:32:35', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'dd174a8a-2586-44aa-9a36-48a609ec9cc4' User entered '23 Aug 2020 12:32'	System	23 Aug 2020 16:32:37
	System	23 Aug 2020 16:32:37

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	20 Aug 2020 17:08:56
User entered 'Day 5'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-24T13:12:27', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '0c3a2a48-3e47-42ae-b74e-2870c9a34e68'	System	24 Aug 2020 17:12:52
User entered 'None (1)'	System	24 Aug 2020 17:12:52

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-24T13:12:30', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '0c3a2a48-3e47-42ae-b74e-2870c9a34e68'	System	24 Aug 2020 17:12:52
User entered 'No (N)'	System	24 Aug 2020 17:12:52

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:08

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-24T13:12:37', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '0c3a2a48-3e47-42ae-b74e-2870c9a34e68'	System	24 Aug 2020 17:12:52
User entered 'No (N)'	System	24 Aug 2020 17:12:52

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-24T13:12:49', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '0c3a2a48-3e47-42ae-b74e-2870c9a34e68'	System	24 Aug 2020 17:12:52
User entered 'None (1)'	System	24 Aug 2020 17:12:52

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-24T13:12:51', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '0c3a2a48-3e47-42ae-b74e-2870c9a34e68'	System	24 Aug 2020 17:12:52
User entered '24 Aug 2020 13:12'	System	24 Aug 2020 17:12:52

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	20 Aug 2020 17:08:56
User entered 'Day 6'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-25T13:16:41', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '9c7c8de9-ac6c-4e6d-8631-3229b6362a22'	System	25 Aug 2020 17:17:12
User entered 'None (1)'	System	25 Aug 2020 17:17:12

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-25T13:16:49', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '9c7c8de9-ac6c-4e6d-8631-3229b6362a22'	System	25 Aug 2020 17:17:12
User entered 'No (N)'	System	25 Aug 2020 17:17:12

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:08

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-25T13:16:53', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '9c7c8de9-ac6c-4e6d-8631-3229b6362a22'	System	25 Aug 2020 17:17:12
User entered 'No (N)'	System	25 Aug 2020 17:17:12

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-25T13:17:05', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '9c7c8de9-ac6c-4e6d-8631-3229b6362a22'	System	25 Aug 2020 17:17:12
User entered 'None (1)'	System	25 Aug 2020 17:17:12

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-25T13:17:08', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '9c7c8de9-ac6c-4e6d-8631-3229b6362a22'	System	25 Aug 2020 17:17:12
User entered '25 Aug 2020 13:17'	System	25 Aug 2020 17:17:12

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	20 Aug 2020 17:08:56
User entered 'Day 7'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-26T16:35:54', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '1123ff45-afd5-4b5d-bd7e-98ac4d6ddca0'	System	26 Aug 2020 20:36:33
User entered 'None (1)'	System	26 Aug 2020 20:36:33

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-26T16:35:57', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '1123ff45-afd5-4b5d-bd7e-98ac4d6ddca0'	System	26 Aug 2020 20:36:33
User entered 'No (N)'	System	26 Aug 2020 20:36:33

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:08

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-26T16:36:04', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '1123ff45-afd5-4b5d-bd7e-98ac4d6ddca0'	System	26 Aug 2020 20:36:33
User entered 'No (N)'	System	26 Aug 2020 20:36:33

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-26T16:36:28', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '1123ff45-afd5-4b5d-bd7e-98ac4d6ddca0'	System	26 Aug 2020 20:36:33
User entered 'None (1)'	System	26 Aug 2020 20:36:33

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-26T16:36:30', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '1123ff45-afd5-4b5d-bd7e-98ac4d6ddca0' User entered '26 Aug 2020 16:36'	System	26 Aug 2020 20:36:33
	System	26 Aug 2020 20:36:33

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	20 Aug 2020 17:08:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-20T13:26:53', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '4c1795f6-6a5c-43bd-90a2-cc4d208bd80d' User entered 'None (0)'	System	20 Aug 2020 17:27:56
	System	20 Aug 2020 17:27:56

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-20T13:26:57', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '4c1795f6-6a5c-43bd-90a2-cc4d208bd80d' User entered 'None (0)'	System	20 Aug 2020 17:27:56
	System	20 Aug 2020 17:27:56

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-20T13:27:03', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '4c1795f6-6a5c-43bd-90a2-cc4d208bd80d' User entered 'None (0)'	System	20 Aug 2020 17:27:56
	System	20 Aug 2020 17:27:56

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-20T13:27:06', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '4c1795f6-6a5c-43bd-90a2-cc4d208bd80d' User entered 'None (0)'	System	20 Aug 2020 17:27:56
	System	20 Aug 2020 17:27:56

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-20T13:27:10', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '4c1795f6-6a5c-43bd-90a2-cc4d208bd80d' User entered 'None (0)'	System	20 Aug 2020 17:27:56
	System	20 Aug 2020 17:27:56

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-20T13:27:18', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '4c1795f6-6a5c-43bd-90a2-cc4d208bd80d' User entered 'None (0)'	System	20 Aug 2020 17:27:56
	System	20 Aug 2020 17:27:56

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-20T13:27:26', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '4c1795f6-6a5c-43bd-90a2-cc4d208bd80d' User entered 'No (N)'	System	20 Aug 2020 17:27:56
	System	20 Aug 2020 17:27:56

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-20T13:27:54', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '4c1795f6-6a5c-43bd-90a2-ec4d208bd80d' User entered '20 Aug 2020 13:27'	System	20 Aug 2020 17:27:56
	System	20 Aug 2020 17:27:56

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '20 Aug 2020 13:26'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '20 Aug 2020 15:56'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	20 Aug 2020 17:08:56
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '20 Aug 2020 16:51'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	20 Aug 2020 17:08:56
User entered 'Day 2'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-21T13:20:18', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '8de6d02c-c1cd-497c-b981-2b8378daa130' User entered 'None (0)'	System	21 Aug 2020 17:20:53
	System	21 Aug 2020 17:20:53

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-21T13:20:26', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '8de6d02c-c1cd-497c-b981-2b8378daa130' User entered 'None (0)'	System	21 Aug 2020 17:20:53
	System	21 Aug 2020 17:20:53

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-21T13:20:32', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '8de6d02c-c1cd-497c-b981-2b8378daa130' User entered 'None (0)'	System	21 Aug 2020 17:20:53
	System	21 Aug 2020 17:20:53

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-21T13:20:37', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '8de6d02c-c1cd-497c-b981-2b8378daa130' User entered 'None (0)'	System	21 Aug 2020 17:20:53
	System	21 Aug 2020 17:20:53

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-21T13:20:41', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '8de6d02c-c1cd-497c-b981-2b8378daa130' User entered 'None (0)'	System	21 Aug 2020 17:20:53
	System	21 Aug 2020 17:20:53

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-21T13:20:44', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '8de6d02c-c1cd-497c-b981-2b8378daa130' User entered 'None (0)'	System	21 Aug 2020 17:20:53
	System	21 Aug 2020 17:20:53

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-21T13:20:48', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '8de6d02c-c1cd-497c-b981-2b8378daa130' User entered 'No (N)'	System	21 Aug 2020 17:20:53
	System	21 Aug 2020 17:20:53

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-21T13:20:51', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '8de6d02c-c1cd-497c-b981-2b8378daa130' User entered '21 Aug 2020 13:20'	System	21 Aug 2020 17:20:53
	System	21 Aug 2020 17:20:53

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	20 Aug 2020 17:08:56
User entered 'Day 3'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-22T15:38:50', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'da69823a-7d2d-4941-aeda-0abdbd228fad' User entered 'None (0)'	System	22 Aug 2020 19:39:14
	System	22 Aug 2020 19:39:14

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-22T15:38:53', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'da69823a-7d2d-4941-aeda-0abdbd228fad' User entered 'None (0)'	System	22 Aug 2020 19:39:14
	System	22 Aug 2020 19:39:14

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-22T15:38:56', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'da69823a-7d2d-4941-aeda-0abdbd228fad' User entered 'None (0)'	System	22 Aug 2020 19:39:14
	System	22 Aug 2020 19:39:14

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-22T15:38:59', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'da69823a-7d2d-4941-aeda-0abdbd228fad' User entered 'None (0)'	System	22 Aug 2020 19:39:14
	System	22 Aug 2020 19:39:14

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-22T15:39:01', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'da69823a-7d2d-4941-aeda-0abdbd228fad' User entered 'None (0)'	System	22 Aug 2020 19:39:14
	System	22 Aug 2020 19:39:14

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-22T15:39:03', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'da69823a-7d2d-4941-aeda-0abdbd228fad' User entered 'None (0)'	System	22 Aug 2020 19:39:14
	System	22 Aug 2020 19:39:14

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-22T15:39:06', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'da69823a-7d2d-4941-aeda-0abdbd228fad' User entered 'No (N)'	System	22 Aug 2020 19:39:14
	System	22 Aug 2020 19:39:14

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-22T15:39:08', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'da69823a-7d2d-4941-aeda-0abdbd228fad' User entered '22 Aug 2020 15:39'	System	22 Aug 2020 19:39:14
	System	22 Aug 2020 19:39:14

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	20 Aug 2020 17:08:56
User entered 'Day 4'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-23T12:31:30', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '9cba2b00-c776-4477-bfd5-fc0540b0ce7d'	System	23 Aug 2020 16:31:55
User entered 'No interference with activity (1)'	System	23 Aug 2020 16:31:55

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-23T12:31:36', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '9cba2b00-c776-4477-bfd5-fc0540b0ce7d' User entered 'None (0)'	System	23 Aug 2020 16:31:55
	System	23 Aug 2020 16:31:55

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-23T12:31:39', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '9cba2b00-c776-4477-bfd5-fc0540b0ce7d' User entered 'None (0)'	System	23 Aug 2020 16:31:55
	System	23 Aug 2020 16:31:55

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-23T12:31:42', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '9cba2b00-c776-4477-bfd5-fc0540b0ce7d' User entered 'None (0)'	System	23 Aug 2020 16:31:55
	System	23 Aug 2020 16:31:55

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-23T12:31:44', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '9cba2b00-c776-4477-bfd5-fc0540b0ce7d' User entered 'None (0)'	System	23 Aug 2020 16:31:55
	System	23 Aug 2020 16:31:55

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-23T12:31:46', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '9cba2b00-c776-4477-bfd5-fc0540b0ce7d' User entered 'None (0)'	System	23 Aug 2020 16:31:55
	System	23 Aug 2020 16:31:55

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-23T12:31:49', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '9cba2b00-c776-4477-bfd5-fc0540b0ce7d' User entered 'No (N)'	System	23 Aug 2020 16:31:55
	System	23 Aug 2020 16:31:55

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-23T12:31:52', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '9cba2b00-c776-4477-bfd5-fc0540b0ce7d' User entered '23 Aug 2020 12:31'	System	23 Aug 2020 16:31:55
	System	23 Aug 2020 16:31:55

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	20 Aug 2020 17:08:56
User entered 'Day 5'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-24T13:11:35', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '708ecab3-e24e-4176-875e-a840782d3e3b' User entered 'None (0)'	System	24 Aug 2020 17:12:06
	System	24 Aug 2020 17:12:06

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-24T13:11:40', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '708ecab3-e24e-4176-875e-a840782d3e3b' User entered 'None (0)'	System	24 Aug 2020 17:12:06
	System	24 Aug 2020 17:12:06

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-24T13:11:44', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '708ecab3-e24e-4176-875e-a840782d3e3b' User entered 'None (0)'	System	24 Aug 2020 17:12:06
	System	24 Aug 2020 17:12:06

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-24T13:11:48', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '708ecab3-e24e-4176-875e-a840782d3e3b' User entered 'None (0)'	System	24 Aug 2020 17:12:06
	System	24 Aug 2020 17:12:06

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-24T13:11:51', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '708ecab3-e24e-4176-875e-a840782d3e3b' User entered 'None (0)'	System	24 Aug 2020 17:12:06
	System	24 Aug 2020 17:12:06

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-24T13:11:54', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '708ecab3-e24e-4176-875e-a840782d3e3b' User entered 'None (0)'	System	24 Aug 2020 17:12:06
	System	24 Aug 2020 17:12:06

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-24T13:12:02', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '708ecab3-e24e-4176-875e-a840782d3e3b' User entered 'No (N)'	System	24 Aug 2020 17:12:06
	System	24 Aug 2020 17:12:06

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-24T13:12:05', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '708ecab3-e24e-4176-875e-a840782d3e3b' User entered '24 Aug 2020 13:12'	System	24 Aug 2020 17:12:06
	System	24 Aug 2020 17:12:06

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	20 Aug 2020 17:08:56
User entered 'Day 6'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-25T13:17:34', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '4864e26a-60c7-41f4-afc9-85ba8dce58e2'	System	25 Aug 2020 17:18:11
User entered 'None (0)'	System	25 Aug 2020 17:18:11

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-25T13:17:39', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '4864e26a-60c7-41f4-afc9-85ba8dce58e2'	System	25 Aug 2020 17:18:11
User entered 'None (0)'	System	25 Aug 2020 17:18:11

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-25T13:17:42', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '4864e26a-60c7-41f4-afc9-85ba8dce58e2'	System	25 Aug 2020 17:18:11
User entered 'None (0)'	System	25 Aug 2020 17:18:11

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-25T13:17:48', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '4864e26a-60c7-41f4-afc9-85ba8dce58e2' User entered 'None (0)'	System	25 Aug 2020 17:18:11
	System	25 Aug 2020 17:18:11

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-25T13:17:51', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '4864e26a-60c7-41f4-afc9-85ba8dce58e2'	System	25 Aug 2020 17:18:11
User entered 'None (0)'	System	25 Aug 2020 17:18:11

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-25T13:17:55', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '4864e26a-60c7-41f4-afc9-85ba8dce58e2'	System	25 Aug 2020 17:18:11
User entered 'None (0)'	System	25 Aug 2020 17:18:11

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-25T13:17:59', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '4864e26a-60c7-41f4-afc9-85ba8dce58e2'	System	25 Aug 2020 17:18:11
User entered 'No (N)'	System	25 Aug 2020 17:18:11

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-25T13:18:08', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '4864e26a-60c7-41f4-afc9-85ba8dce58e2'	System	25 Aug 2020 17:18:11
User entered '25 Aug 2020 13:18'	System	25 Aug 2020 17:18:11

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	20 Aug 2020 17:08:56
User entered 'Day 7'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-26T16:36:33', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'a53b34ee-4776-4714-9f49-880509248850' User entered 'None (0)'	System	26 Aug 2020 20:37:11
	System	26 Aug 2020 20:37:11

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-26T16:36:36', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'a53b34ee-4776-4714-9f49-880509248850' User entered 'None (0)'	System	26 Aug 2020 20:37:11
	System	26 Aug 2020 20:37:11

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-26T16:36:47', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'a53b34ee-4776-4714-9f49-880509248850' User entered 'None (0)'	System	26 Aug 2020 20:37:11
	System	26 Aug 2020 20:37:11

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-26T16:36:59', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'a53b34ee-4776-4714-9f49-880509248850' User entered 'None (0)'	System	26 Aug 2020 20:37:11
	System	26 Aug 2020 20:37:11

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-26T16:37:01', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'a53b34ee-4776-4714-9f49-880509248850' User entered 'None (0)'	System	26 Aug 2020 20:37:11
	System	26 Aug 2020 20:37:11

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-26T16:37:03', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'a53b34ee-4776-4714-9f49-880509248850' User entered 'None (0)'	System	26 Aug 2020 20:37:11
	System	26 Aug 2020 20:37:11

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-26T16:37:05', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'a53b34ee-4776-4714-9f49-880509248850' User entered 'No (N)'	System	26 Aug 2020 20:37:11
	System	26 Aug 2020 20:37:11

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-08-26T16:37:09', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'a53b34ee-4776-4714-9f49-880509248850' User entered '26 Aug 2020 16:37'	System	26 Aug 2020 20:37:11
	System	26 Aug 2020 20:37:11

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 17:08:56

US3542030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 17:08:56

US3542030

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 15:27:04
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	31 Aug 2020 16:57:05

US3542030

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	05 Sep 2020 15:27:04
User entered '28 Aug 2020'	(b) (4) Taylor Ladson (b) (4)	31 Aug 2020 16:57:05
	(b) (4)	

US3542030

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 15:27:04
User entered 'Contact Made (CONTACT MADE)'	Taylor Ladson (b) (4) (b) (4)	31 Aug 2020 16:57:05

US3542030

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	05 Sep 2020 15:27:04
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	31 Aug 2020 16:57:05

US3542030

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 15:27:04
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	31 Aug 2020 16:57:10

US3542030

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered 'l'	System	31 Aug 2020 16:57:10

US3542030

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	09 Sep 2020 01:41:06
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	08 Sep 2020 17:38:38

US3542030

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	09 Sep 2020 01:41:06
User entered '4 Sep 2020'	(b) (4) Madhu Balachandran (b) (4)	08 Sep 2020 17:38:38

US3542030

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	09 Sep 2020 01:41:06
User entered 'Contact Made (CONTACT MADE)'	Madhu Balachandran (b) (4)	08 Sep 2020 17:38:38

US3542030

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	09 Sep 2020 01:41:06
User entered empty.	Madhu Balachandran (b) (4)	08 Sep 2020 17:38:38

US3542030

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	09 Sep 2020 01:41:06
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	08 Sep 2020 17:38:46

US3542030

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered 'I'	System	08 Sep 2020 17:38:46

US3542030

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	17 Sep 2020 04:15:17
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	14 Sep 2020 17:07:28

US3542030

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	17 Sep 2020 04:15:17
User entered '11 Sep 2020'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:07:28

US3542030

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	17 Sep 2020 04:15:17
User entered 'Contact Made (CONTACT MADE)'	Madhu Balachandran (b) (4)	14 Sep 2020 17:07:28

US3542030

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	17 Sep 2020 04:15:17
User entered empty.	Madhu Balachandran (b) (4)	14 Sep 2020 17:07:28

US3542030

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	17 Sep 2020 04:15:17
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	14 Sep 2020 17:07:40

US3542030

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered 'l'	System	14 Sep 2020 17:07:40

US3542030

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	29 Sep 2020 04:14:17
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	25 Sep 2020 18:32:41

US3542030

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	29 Sep 2020 04:14:17
User entered '24 Sep 2020'	Taylor Ladson (b) (4) (b) (4)	25 Sep 2020 18:32:41

US3542030

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	29 Sep 2020 04:14:17
User entered 'Clinic (Clinic)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	25 Sep 2020 18:32:41

US3542030

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered 'VISIT2'	System	25 Sep 2020 18:32:41

US3542030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User accepted default value 'Pre-Dose (PREDOSE)'	Taylor Ladson (u) (4) (b) (4)	25 Sep 2020 18:39:07

US3542030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	29 Sep 2020 04:14:17
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	25 Sep 2020 18:39:07

US3542030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	29 Sep 2020 04:14:17
User entered '24 Sep 2020'	(b) (4) Taylor Ladson (b) (4)	25 Sep 2020 18:39:07
	(b) (4)	

US3542030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	29 Sep 2020 04:14:17
User entered '09:10'	Taylor Ladson (b) (4) (b) (4)	25 Sep 2020 18:39:07

US3542030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered '24 Sep 2020 09:10'	System	25 Sep 2020 18:39:07

US3542030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	29 Sep 2020 04:14:17
User entered '98.2' F	(b) (4) Taylor Ladson (b) (4)	25 Sep 2020 18:39:07

US3542030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	29 Sep 2020 04:14:17
User entered 'Oral (Oral)'	Taylor Ladson (b) (4) (b) (4)	25 Sep 2020 18:39:07

US3542030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	29 Sep 2020 04:14:17
User entered empty.	Taylor Ladson (b) (4) (b) (4)	25 Sep 2020 18:39:07

US3542030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	29 Sep 2020 04:14:17
User entered '94'	Taylor Ladson (b) (4) (b) (4)	25 Sep 2020 18:39:07

US3542030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered 'bpm'	System	25 Sep 2020 18:39:07

US3542030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	29 Sep 2020 04:14:17
User entered '16'	Taylor Ladson (b) (4) (b) (4)	25 Sep 2020 18:39:07

US3542030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered 'breaths/min'	System	25 Sep 2020 18:39:07

US3542030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	29 Sep 2020 04:14:17
User entered '119'	Taylor Ladson (b) (4) (b) (4)	25 Sep 2020 18:39:07

US3542030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered 'mmHg'	System	25 Sep 2020 18:39:07

US3542030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	29 Sep 2020 04:14:17
User entered '78'	Taylor Ladson (b) (4) (b) (4)	25 Sep 2020 18:39:07

US3542030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered 'mmHg'	System	25 Sep 2020 18:39:07

US3542030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User accepted default value 'Post-Dose (POSTDOSE)'	Taylor Ladson (u) (4) (b) (4)	25 Sep 2020 18:40:22

US3542030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	29 Sep 2020 04:14:17
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	25 Sep 2020 18:40:22

US3542030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	29 Sep 2020 04:14:17
User entered '24 Sep 2020'	(b) (4) Taylor Ladson (b) (4)	25 Sep 2020 18:40:22
	(b) (4)	

US3542030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	29 Sep 2020 04:14:17
User entered '11:13'	Taylor Ladson (b) (4) (b) (4)	25 Sep 2020 18:40:22

US3542030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered '24 Sep 2020 11:13'	System	25 Sep 2020 18:40:22

US3542030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	29 Sep 2020 04:14:17
User entered '98.4' F	(b) (4) Taylor Ladson (b) (4)	25 Sep 2020 18:40:22

US3542030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	29 Sep 2020 04:14:17
User entered 'Oral (Oral)'	Taylor Ladson (b) (4) (b) (4)	25 Sep 2020 18:40:22

US3542030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	29 Sep 2020 04:14:17
User entered empty.	Taylor Ladson (b) (4) (b) (4)	25 Sep 2020 18:40:22

US3542030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	29 Sep 2020 04:14:17
User entered '86'	Taylor Ladson (b) (4) (b) (4)	25 Sep 2020 18:40:22

US3542030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered 'bpm'	System	25 Sep 2020 18:40:22

US3542030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	29 Sep 2020 04:14:17
User entered '16'	Taylor Ladson (b) (4) (b) (4)	25 Sep 2020 18:40:22

US3542030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered 'breaths/min'	System	25 Sep 2020 18:40:22

US3542030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	29 Sep 2020 04:14:17
User entered '132'	Taylor Ladson (b) (4) (b) (4)	25 Sep 2020 18:40:22

US3542030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered 'mmHg'	System	25 Sep 2020 18:40:22

US3542030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	29 Sep 2020 04:14:17
User entered '83'	Taylor Ladson (b) (4) (b) (4)	25 Sep 2020 18:40:22

US3542030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered 'mmHg'	System	25 Sep 2020 18:40:22

US3542030

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	29 Sep 2020 04:14:17
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	25 Sep 2020 18:36:39
	(b) (4)	

US3542030

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	29 Sep 2020 04:14:17
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	25 Sep 2020 18:36:44
User entered '24 Sep 2020' reason for change: Data Entry Error	Taylor Ladson (b) (4) (b) (4)	25 Sep 2020 18:36:44
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	25 Sep 2020 18:36:39
User entered '23 Sep 2020'	Taylor Ladson (b) (4) (b) (4)	25 Sep 2020 18:36:39

US3542030

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	29 Sep 2020 04:14:17
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	25 Sep 2020 18:36:58

US3542030

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	29 Sep 2020 04:14:17
User entered '24 Sep 2020'	(b) (4)	
	Taylor Ladson (b) (4)	25 Sep 2020 18:36:58
	(b) (4)	

US3542030

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	29 Sep 2020 04:14:17
User entered 'Urine (URINE)'	(b) (4) Taylor Ladson (b) (4)	25 Sep 2020 18:36:58
	(b) (4)	

US3542030

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	29 Sep 2020 04:14:17
User entered 'Negative (NEGATIVE)'	(b) (4) Taylor Ladson (b) (4)	25 Sep 2020 18:36:58
	(b) (4)	

US3542030

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	29 Sep 2020 04:14:17
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	25 Sep 2020 18:36:58

US3542030

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	29 Sep 2020 04:14:17
User entered empty.	Taylor Ladson (b) (4) (b) (4)	25 Sep 2020 18:36:58

US3542030

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	29 Sep 2020 04:14:17
User entered empty.	Taylor Ladson (b) (4) (b) (4)	25 Sep 2020 18:36:58

US3542030

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered empty.	System	25 Sep 2020 18:36:58

US3542030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:53:16

US3542030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	29 Sep 2020 04:14:17
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:53:16

US3542030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	29 Sep 2020 04:14:17
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:53:16

US3542030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered 'MRNA-1273 OR PLACEBO'	System	24 Sep 2020 14:53:16

US3542030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	29 Sep 2020 04:14:17
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:53:16

US3542030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	29 Sep 2020 04:14:17
User entered '10:40'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:53:16

US3542030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered '24 Sep 2020 10:40'	System	24 Sep 2020 14:53:16

US3542030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	29 Sep 2020 04:14:17
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:53:16

US3542030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered 'ONCE'	System	24 Sep 2020 14:53:16

US3542030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered 'INTRAMUSCULAR'	System	24 Sep 2020 14:53:16

US3542030

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	29 Sep 2020 04:14:17
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	25 Sep 2020 18:39:27

US3542030

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	29 Sep 2020 04:14:17
User entered '24 Sep 2020'	Taylor Ladson (b) (4) (b) (4)	25 Sep 2020 18:39:27

US3542030

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	29 Sep 2020 04:14:17
User entered '09:50'	Taylor Ladson (b) (4) (b) (4)	25 Sep 2020 18:39:27

US3542030

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:08

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered '24 Sep 2020 09:50'	System	25 Sep 2020 18:39:27

US3542030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:12:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	29 Sep 2020 04:14:17
User entered '24 Sep 2020'	(b) (4) Taylor Ladson (b) (4)	25 Sep 2020 18:39:41
	(b) (4)	

US3542030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:12:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Taylor Ladson (u) (4) (b) (4)	25 Sep 2020 18:39:41

US3542030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:12:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	29 Sep 2020 04:14:17
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	25 Sep 2020 18:39:41

US3542030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:12:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	29 Sep 2020 04:14:17
User entered '09:58'	(b) (4) Taylor Ladson (b) (4)	25 Sep 2020 18:39:41
	(b) (4)	

US3542030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:12:08

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered '24 Sep 2020 09:58'	System	25 Sep 2020 18:39:41

US3542030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:12:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Taylor Ladson (u) (4) (b) (4)	25 Sep 2020 18:39:45

US3542030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:12:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	29 Sep 2020 04:14:17
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	25 Sep 2020 18:39:45

US3542030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:12:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	29 Sep 2020 04:14:17
User entered empty.	(b) (4) Taylor Ladson (b) (4)	25 Sep 2020 18:39:45

US3542030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:12:08

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered empty.	System	25 Sep 2020 18:39:45

US3542030

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	29 Sep 2020 04:14:17
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	25 Sep 2020 18:39:50

US3542030

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered 'I'	System	25 Sep 2020 18:39:50

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	24 Sep 2020 14:53:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-24T11:12:54', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '9b05ce0d-21da-4a2d-9aaa-0047325fb6c2' User entered 'Yes (Y)'	System	24 Sep 2020 15:13:07
	System	24 Sep 2020 15:13:07

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-24T11:12:58', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '9b05ce0d-21da-4a2d-9aaa-0047325fb6c2' User entered '98.4'	System	24 Sep 2020 15:13:07
	System	24 Sep 2020 15:13:07

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-24T11:13:02', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '9b05ce0d-21da-4a2d-9aaa-0047325fb6c2'	System	24 Sep 2020 15:13:07
User entered 'No (N)'	System	24 Sep 2020 15:13:07

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-24T11:13:05', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '9b05ce0d-21da-4a2d-9aaa-0047325fb6c2'	System	24 Sep 2020 15:13:07
User entered '24 Sep 2020 11:13'	System	24 Sep 2020 15:13:07

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '24 Sep 2020 11:00'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '24 Sep 2020 13:30'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	24 Sep 2020 14:53:16
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-24T22:27:46', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '3f8c5d54-07f6-41fc-baea-2079b1ff5d97'	System	25 Sep 2020 02:28:56
User entered 'Yes (Y)'	System	25 Sep 2020 02:28:56

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-24T22:28:45', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '3f8c5d54-07f6-41fc-baea-2079b1ff5d97' User entered '97.4'	System	25 Sep 2020 02:28:56
	System	25 Sep 2020 02:28:56

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-24T22:28:49', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '3f8c5d54-07f6-41fc-baea-2079b1ff5d97'	System	25 Sep 2020 02:28:56
User entered 'No (N)'	System	25 Sep 2020 02:28:56

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-24T22:28:53', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '3f8c5d54-07f6-41fc-baea-2079b1ff5d97'	System	25 Sep 2020 02:28:56
User entered '24 Sep 2020 22:28'	System	25 Sep 2020 02:28:56

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '24 Sep 2020 14:25'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	24 Sep 2020 14:53:16
User entered 'Day 2'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-25T14:15:48', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '4668a327-86fa-4b28-afe9-8dde8e5a93e5' User entered 'Yes (Y)'	System	25 Sep 2020 18:16:05
	System	25 Sep 2020 18:16:05

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-25T14:15:54', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '4668a327-86fa-4b28-afe9-8dde8e5a93e5' User entered '97.5'	System	25 Sep 2020 18:16:05
	System	25 Sep 2020 18:16:05

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:08

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-25T14:15:57', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '4668a327-86fa-4b28-afe9-8dde8e5a93e5'	System	25 Sep 2020 18:16:05
User entered 'No (N)'	System	25 Sep 2020 18:16:05

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-25T14:16:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '4668a327-86fa-4b28-afe9-8dde8e5a93e5'	System	25 Sep 2020 18:16:05
User entered '25 Sep 2020 14:16'	System	25 Sep 2020 18:16:05

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	24 Sep 2020 14:53:16
User entered 'Day 3'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-26T12:40:40', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '8673423b-1b9a-4ade-9fe7-e5ec69d6fbf7' User entered 'Yes (Y)'	System	26 Sep 2020 16:40:54
	System	26 Sep 2020 16:40:54

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-26T12:40:45', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '8673423b-1b9a-4ade-9fe7-e5ec69d6fbf7' User entered '98.1'	System	26 Sep 2020 16:40:54
	System	26 Sep 2020 16:40:54

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:08

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-26T12:40:48', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '8673423b-1b9a-4ade-9fe7-e5ec69d6fbf7'	System	26 Sep 2020 16:40:54
User entered 'No (N)'	System	26 Sep 2020 16:40:54

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-26T12:40:51', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '8673423b-1b9a-4ade-9fe7-e5ec69d6fbf7' User entered '26 Sep 2020 12:40'	System	26 Sep 2020 16:40:54
	System	26 Sep 2020 16:40:54

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	24 Sep 2020 14:53:16
User entered 'Day 4'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-27T14:59:58', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'ba356136-81a3-480b-8ee4-e2813c9af428' User entered 'Yes (Y)'	System	27 Sep 2020 19:01:42
	System	27 Sep 2020 19:01:42

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-27T15:01:34', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'ba356136-81a3-480b-8ee4-e2813c9af428' User entered '97.9'	System	27 Sep 2020 19:01:42
	System	27 Sep 2020 19:01:42

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:08

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-27T15:01:37', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'ba356136-81a3-480b-8ee4-e2813c9af428'	System	27 Sep 2020 19:01:42
User entered 'No (N)'	System	27 Sep 2020 19:01:42

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-27T15:01:39', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'ba356136-81a3-480b-8ee4-e2813c9af428' User entered '27 Sep 2020 15:01'	System	27 Sep 2020 19:01:42
	System	27 Sep 2020 19:01:42

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	24 Sep 2020 14:53:16
User entered 'Day 5'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-28T13:52:10', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '3b1b7fbb-0c73-466c-a7c5-523ffd6c98be' User entered 'Yes (Y)'	System	28 Sep 2020 17:52:31
	System	28 Sep 2020 17:52:31

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-28T13:52:23', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '3b1b7fbb-0c73-466c-a7c5-523ffd6c98be' User entered '97.5'	System	28 Sep 2020 17:52:31
	System	28 Sep 2020 17:52:31

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:08

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-28T13:52:26', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '3b1b7fbb-0c73-466c-a7c5-523ffd6c98be' User entered 'No (N)'	System	28 Sep 2020 17:52:31
	System	28 Sep 2020 17:52:31

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-28T13:52:28', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '3b1b7fbb-0c73-466c-a7c5-523ffd6c98be' User entered '28 Sep 2020 13:52'	System	28 Sep 2020 17:52:31
	System	28 Sep 2020 17:52:31

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	24 Sep 2020 14:53:16
User entered 'Day 6'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-29T12:12:35', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '512bb6a3-5079-47ec-af59-8960593a8ba9' User entered 'Yes (Y)'	System	29 Sep 2020 16:12:47
	System	29 Sep 2020 16:12:47

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-29T12:12:39', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '512bb6a3-5079-47ec-af59-8960593a8ba9' User entered '97.9'	System	29 Sep 2020 16:12:47
	System	29 Sep 2020 16:12:47

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:08

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-29T12:12:43', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '512bb6a3-5079-47ec-af59-8960593a8ba9' User entered 'No (N)'	System	29 Sep 2020 16:12:47
	System	29 Sep 2020 16:12:47

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-29T12:12:45', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '512bb6a3-5079-47ec-af59-8960593a8ba9' User entered '29 Sep 2020 12:12'	System	29 Sep 2020 16:12:47
	System	29 Sep 2020 16:12:47

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	24 Sep 2020 14:53:16
User entered 'Day 7'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-30T13:44:53', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'ec9477fa-1b84-4092-856f-df82ee707139'	System	30 Sep 2020 17:45:33
User entered 'Yes (Y)'	System	30 Sep 2020 17:45:33

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-30T13:45:13', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'ec9477fa-1b84-4092-856f-df82ee707139' User entered '97.5'	System	30 Sep 2020 17:45:33
	System	30 Sep 2020 17:45:33

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:08

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-30T13:45:19', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'ec9477fa-1b84-4092-856f-df82ee707139'	System	30 Sep 2020 17:45:33
User entered 'No (N)'	System	30 Sep 2020 17:45:33

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-30T13:45:21', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'ec9477fa-1b84-4092-856f-df82ee707139' User entered '30 Sep 2020 13:45'	System	30 Sep 2020 17:45:33
	System	30 Sep 2020 17:45:33

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	24 Sep 2020 14:53:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-24T11:16:52', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '212b45e7-e868-4dd0-b126-5fa62a1c09de' User entered 'None (1)'	System	24 Sep 2020 15:17:09
	System	24 Sep 2020 15:17:09

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-24T11:16:54', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '212b45e7-e868-4dd0-b126-5fa62a1c09de' User entered 'No (N)'	System	24 Sep 2020 15:17:09
	System	24 Sep 2020 15:17:09

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-24T11:17:01', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '212b45e7-e868-4dd0-b126-5fa62a1c09de' User entered 'No (N)'	System	24 Sep 2020 15:17:09
	System	24 Sep 2020 15:17:09

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-24T11:17:05', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '212b45e7-e868-4dd0-b126-5fa62a1c09de' User entered 'None (1)'	System	24 Sep 2020 15:17:09
	System	24 Sep 2020 15:17:09

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-24T11:17:08', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '212b45e7-e868-4dd0-b126-5fa62a1c09de' User entered '24 Sep 2020 11:17'	System	24 Sep 2020 15:17:09
	System	24 Sep 2020 15:17:09

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '24 Sep 2020 11:00'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '24 Sep 2020 13:30'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	24 Sep 2020 14:53:16
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-24T22:06:34', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '5b6f9288-648d-4d20-9f8a-89fe2398b22c' User entered 'None (1)'	System	25 Sep 2020 02:07:44
	System	25 Sep 2020 02:07:44

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-24T22:06:39', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '5b6f9288-648d-4d20-9f8a-89fe2398b22c'	System	25 Sep 2020 02:07:44
User entered 'No (N)'	System	25 Sep 2020 02:07:44

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-24T22:07:29', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '5b6f9288-648d-4d20-9f8a-89fe2398b22c' User entered 'No (N)'	System	25 Sep 2020 02:07:44
	System	25 Sep 2020 02:07:44

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-24T22:07:40', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '5b6f9288-648d-4d20-9f8a-89fe2398b22c' User entered 'None (1)'	System	25 Sep 2020 02:07:44
	System	25 Sep 2020 02:07:44

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-24T22:07:43', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '5b6f9288-648d-4d20-9f8a-89fe2398b22c' User entered '24 Sep 2020 22:07'	System	25 Sep 2020 02:07:44
	System	25 Sep 2020 02:07:44

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '24 Sep 2020 14:25'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	24 Sep 2020 14:53:16
User entered 'Day 2'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-25T14:16:14', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '28b22c17-c560-402f-b68e-241d00e7badb' User entered 'None (1)'	System	25 Sep 2020 18:17:14
	System	25 Sep 2020 18:17:14

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-25T14:16:26', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '28b22c17-c560-402f-b68e-241d00e7badb' User entered 'No (N)'	System	25 Sep 2020 18:17:14
	System	25 Sep 2020 18:17:14

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:08

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-25T14:16:40', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '28b22c17-c560-402f-b68e-241d00e7badb' User entered 'No (N)'	System	25 Sep 2020 18:17:14
	System	25 Sep 2020 18:17:14

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-25T14:16:47', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '28b22c17-c560-402f-b68e-241d00e7badb' User entered 'None (1)'	System	25 Sep 2020 18:17:14
	System	25 Sep 2020 18:17:14

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-25T14:17:11', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '28b22c17-c560-402f-b68e-241d00e7badb' User entered '25 Sep 2020 14:17'	System	25 Sep 2020 18:17:14
	System	25 Sep 2020 18:17:14

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	24 Sep 2020 14:53:16
User entered 'Day 3'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-26T12:32:59', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '399dd87a-e6f1-481f-ba2b-c3dbe845e9b8' User entered 'None (1)'	System	26 Sep 2020 16:33:20
	System	26 Sep 2020 16:33:20

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-26T12:33:02', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '399dd87a-e6f1-481f-ba2b-c3dbe845e9b8' User entered 'No (N)'	System	26 Sep 2020 16:33:20
	System	26 Sep 2020 16:33:20

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:08

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-26T12:33:06', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '399dd87a-e6f1-481f-ba2b-c3dbe845e9b8'	System	26 Sep 2020 16:33:20
User entered 'No (N)'	System	26 Sep 2020 16:33:20

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-26T12:33:15', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '399dd87a-e6f1-481f-ba2b-c3dbe845e9b8' User entered 'None (1)'	System	26 Sep 2020 16:33:20
	System	26 Sep 2020 16:33:20

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-26T12:33:17', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '399dd87a-e6f1-481f-ba2b-c3dbe845e9b8' User entered '26 Sep 2020 12:33'	System	26 Sep 2020 16:33:20
	System	26 Sep 2020 16:33:20

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	24 Sep 2020 14:53:16
User entered 'Day 4'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-27T14:58:16', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '0c2966ec-488b-4961-a411-92636f1a1fe0' User entered 'None (1)'	System	27 Sep 2020 18:58:45
	System	27 Sep 2020 18:58:45

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-27T14:58:19', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '0c2966ec-488b-4961-a411-92636f1a1fe0' User entered 'No (N)'	System	27 Sep 2020 18:58:45
	System	27 Sep 2020 18:58:45

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:08

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-27T14:58:33', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '0c2966ec-488b-4961-a411-92636f1a1fe0' User entered 'No (N)'	System	27 Sep 2020 18:58:45
	System	27 Sep 2020 18:58:45

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-27T14:58:41', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '0c2966ec-488b-4961-a411-92636f1a1fe0' User entered 'None (1)'	System	27 Sep 2020 18:58:45
	System	27 Sep 2020 18:58:45

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-27T14:58:44', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '0c2966ec-488b-4961-a411-92636f1a1fe0' User entered '27 Sep 2020 14:58'	System	27 Sep 2020 18:58:45
	System	27 Sep 2020 18:58:45

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	24 Sep 2020 14:53:16
User entered 'Day 5'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-28T13:29:22', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '9a3b57e5-dc7f-4d7d-a70a-1de2e8ea01f2'	System	28 Sep 2020 17:29:44
User entered 'None (1)'	System	28 Sep 2020 17:29:44

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-28T13:29:28', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '9a3b57e5-dc7f-4d7d-a70a-1de2e8ea01f2'	System	28 Sep 2020 17:29:44
User entered 'No (N)'	System	28 Sep 2020 17:29:44

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:08

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-28T13:29:31', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '9a3b57e5-dc7f-4d7d-a70a-1de2e8ea01f2'	System	28 Sep 2020 17:29:44
User entered 'No (N)'	System	28 Sep 2020 17:29:44

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-28T13:29:34', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '9a3b57e5-dc7f-4d7d-a70a-1de2e8ea01f2'	System	28 Sep 2020 17:29:44
User entered 'None (1)'	System	28 Sep 2020 17:29:44

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-28T13:29:42', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '9a3b57e5-dc7f-4d7d-a70a-1de2e8ea01f2' User entered '28 Sep 2020 13:29'	System	28 Sep 2020 17:29:44
	System	28 Sep 2020 17:29:44

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	24 Sep 2020 14:53:16
User entered 'Day 6'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-29T12:04:09', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'a0c06f58-2626-4b65-81e4-b61150fb3691' User entered 'None (1)'	System	29 Sep 2020 16:04:28
	System	29 Sep 2020 16:04:28

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-29T12:04:11', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'a0c06f58-2626-4b65-81e4-b61150fb3691' User entered 'No (N)'	System	29 Sep 2020 16:04:28
	System	29 Sep 2020 16:04:28

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:08

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-29T12:04:13', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'a0c06f58-2626-4b65-81e4-b61150fb3691' User entered 'No (N)'	System	29 Sep 2020 16:04:28
	System	29 Sep 2020 16:04:28

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-29T12:04:24', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'a0c06f58-2626-4b65-81e4-b61150fb3691' User entered 'None (1)'	System	29 Sep 2020 16:04:28
	System	29 Sep 2020 16:04:28

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-29T12:04:26', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'a0c06f58-2626-4b65-81e4-b61150fb3691' User entered '29 Sep 2020 12:04'	System	29 Sep 2020 16:04:28
	System	29 Sep 2020 16:04:28

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	24 Sep 2020 14:53:16
User entered 'Day 7'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-30T13:43:46', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '970b3c12-ba75-4274-928a-fe89c2f21454'	System	30 Sep 2020 17:44:08
User entered 'None (1)'	System	30 Sep 2020 17:44:08

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-30T13:43:50', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '970b3c12-ba75-4274-928a-fe89c2f21454' User entered 'No (N)'	System	30 Sep 2020 17:44:08
	System	30 Sep 2020 17:44:08

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:08

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-30T13:43:53', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '970b3c12-ba75-4274-928a-fe89c2f21454' User entered 'No (N)'	System	30 Sep 2020 17:44:08
	System	30 Sep 2020 17:44:08

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-30T13:44:01', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '970b3c12-ba75-4274-928a-fe89c2f21454' User entered 'None (1)'	System	30 Sep 2020 17:44:08
	System	30 Sep 2020 17:44:08

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-30T13:44:03', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '970b3c12-ba75-4274-928a-fe89c2f21454' User entered '30 Sep 2020 13:44'	System	30 Sep 2020 17:44:08
	System	30 Sep 2020 17:44:08

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	24 Sep 2020 14:53:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-24T11:17:40', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'e900af5b-6d76-4527-99aa-febc9d546c0b' User entered 'None (0)'	System	24 Sep 2020 15:18:24
	System	24 Sep 2020 15:18:24

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-24T11:17:47', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'e900af5b-6d76-4527-99aa-febc9d546c0b' User entered 'None (0)'	System	24 Sep 2020 15:18:24
	System	24 Sep 2020 15:18:24

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-24T11:18:08', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'e900af5b-6d76-4527-99aa-febc9d546c0b' User entered 'None (0)'	System	24 Sep 2020 15:18:24
	System	24 Sep 2020 15:18:24

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-24T11:18:11', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'e900af5b-6d76-4527-99aa-febc9d546c0b' User entered 'None (0)'	System	24 Sep 2020 15:18:24
	System	24 Sep 2020 15:18:24

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-24T11:18:13', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'e900af5b-6d76-4527-99aa-febc9d546c0b' User entered 'None (0)'	System	24 Sep 2020 15:18:24
	System	24 Sep 2020 15:18:24

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-24T11:18:15', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'e900af5b-6d76-4527-99aa-febc9d546c0b' User entered 'None (0)'	System	24 Sep 2020 15:18:24
	System	24 Sep 2020 15:18:24

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-24T11:18:20', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'e900af5b-6d76-4527-99aa-febc9d546c0b' User entered 'No (N)'	System	24 Sep 2020 15:18:24
	System	24 Sep 2020 15:18:24

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-24T11:18:22', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'e900af5b-6d76-4527-99aa-febc9d546c0b' User entered '24 Sep 2020 11:18'	System	24 Sep 2020 15:18:24
	System	24 Sep 2020 15:18:24

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '24 Sep 2020 11:00'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '24 Sep 2020 13:30'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	24 Sep 2020 14:53:16
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-24T22:07:50', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'cb273dff-4738-43cc-9de7-8f90b1d0c3ac' User entered 'None (0)'	System	25 Sep 2020 02:08:10
	System	25 Sep 2020 02:08:10

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-24T22:07:53', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'cb273dff-4738-43cc-9de7-8f90b1d0c3ac' User entered 'None (0)'	System	25 Sep 2020 02:08:10
	System	25 Sep 2020 02:08:10

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-24T22:07:55', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'cb273dff-4738-43cc-9de7-8f90b1d0c3ac' User entered 'None (0)'	System	25 Sep 2020 02:08:10
	System	25 Sep 2020 02:08:10

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-24T22:07:57', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'cb273dff-4738-43cc-9de7-8f90b1d0c3ac' User entered 'None (0)'	System	25 Sep 2020 02:08:10
	System	25 Sep 2020 02:08:10

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-24T22:07:59', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'cb273dff-4738-43cc-9de7-8f90b1d0c3ac' User entered 'None (0)'	System	25 Sep 2020 02:08:10
	System	25 Sep 2020 02:08:10

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-24T22:08:01', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'cb273dff-4738-43cc-9de7-8f90b1d0c3ac'	System	25 Sep 2020 02:08:10
User entered 'None (0)'	System	25 Sep 2020 02:08:10

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-24T22:08:05', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'cb273dff-4738-43cc-9de7-8f90b1d0c3ac'	System	25 Sep 2020 02:08:10
User entered 'No (N)'	System	25 Sep 2020 02:08:10

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-24T22:08:07', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'cb273dff-4738-43cc-9de7-8f90b1d0c3ac'	System	25 Sep 2020 02:08:10
User entered '24 Sep 2020 22:08'	System	25 Sep 2020 02:08:10

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '24 Sep 2020 14:25'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	24 Sep 2020 14:53:16
User entered 'Day 2'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-25T14:15:25', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '034282cc-59a7-450d-9cb9-162d0dec0414' User entered 'None (0)'	System	25 Sep 2020 18:15:44
	System	25 Sep 2020 18:15:44

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-25T14:15:27', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '034282cc-59a7-450d-9cb9-162d0dec0414' User entered 'None (0)'	System	25 Sep 2020 18:15:44
	System	25 Sep 2020 18:15:44

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-25T14:15:29', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '034282cc-59a7-450d-9cb9-162d0dec0414' User entered 'None (0)'	System	25 Sep 2020 18:15:44
	System	25 Sep 2020 18:15:44

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-25T14:15:31', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '034282cc-59a7-450d-9cb9-162d0dec0414' User entered 'None (0)'	System	25 Sep 2020 18:15:44
	System	25 Sep 2020 18:15:44

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-25T14:15:33', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '034282cc-59a7-450d-9cb9-162d0dec0414' User entered 'None (0)'	System	25 Sep 2020 18:15:44
	System	25 Sep 2020 18:15:44

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-25T14:15:35', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '034282cc-59a7-450d-9cb9-162d0dec0414' User entered 'None (0)'	System	25 Sep 2020 18:15:44
	System	25 Sep 2020 18:15:44

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-25T14:15:38', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '034282cc-59a7-450d-9cb9-162d0dec0414' User entered 'No (N)'	System	25 Sep 2020 18:15:44
	System	25 Sep 2020 18:15:44

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-25T14:15:40', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '034282cc-59a7-450d-9cb9-162d0dec0414' User entered '25 Sep 2020 14:15'	System	25 Sep 2020 18:15:44
	System	25 Sep 2020 18:15:44

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	24 Sep 2020 14:53:16
User entered 'Day 3'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-26T12:32:16', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'b10e8b6c-50c7-4372-9aab-2be1fc4e3695'	System	26 Sep 2020 16:32:39
User entered 'None (0)'	System	26 Sep 2020 16:32:39

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-26T12:32:21', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'b10e8b6c-50c7-4372-9aab-2be1fc4e3695'	System	26 Sep 2020 16:32:39
User entered 'None (0)'	System	26 Sep 2020 16:32:39

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-26T12:32:24', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'b10e8b6c-50c7-4372-9aab-2be1fc4e3695'	System	26 Sep 2020 16:32:39
User entered 'None (0)'	System	26 Sep 2020 16:32:39

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-26T12:32:26', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'b10e8b6c-50c7-4372-9aab-2be1fc4e3695' User entered 'None (0)'	System	26 Sep 2020 16:32:39
	System	26 Sep 2020 16:32:39

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-26T12:32:28', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'b10e8b6c-50c7-4372-9aab-2be1fc4e3695' User entered 'None (0)'	System	26 Sep 2020 16:32:39
	System	26 Sep 2020 16:32:39

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-26T12:32:30', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'b10e8b6c-50c7-4372-9aab-2be1fc4e3695'	System	26 Sep 2020 16:32:39
User entered 'None (0)'	System	26 Sep 2020 16:32:39

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-26T12:32:33', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'b10e8b6c-50c7-4372-9aab-2be1fc4e3695'	System	26 Sep 2020 16:32:39
User entered 'No (N)'	System	26 Sep 2020 16:32:39

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-26T12:32:36', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'b10e8b6c-50c7-4372-9aab-2be1fc4e3695' User entered '26 Sep 2020 12:32'	System	26 Sep 2020 16:32:39
	System	26 Sep 2020 16:32:39

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	24 Sep 2020 14:53:16
User entered 'Day 4'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-27T14:57:12', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'da39638e-6d3f-4ed8-95cb-90517fdc07c0' User entered 'None (0)'	System	27 Sep 2020 18:58:08
	System	27 Sep 2020 18:58:08

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-27T14:57:29', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'da39638e-6d3f-4ed8-95cb-90517fdc07c0' User entered 'None (0)'	System	27 Sep 2020 18:58:08
	System	27 Sep 2020 18:58:08

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-27T14:57:37', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'da39638e-6d3f-4ed8-95cb-90517fdc07c0' User entered 'None (0)'	System	27 Sep 2020 18:58:08
	System	27 Sep 2020 18:58:08

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-27T14:57:45', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'da39638e-6d3f-4ed8-95cb-90517fdc07c0' User entered 'None (0)'	System	27 Sep 2020 18:58:08
	System	27 Sep 2020 18:58:08

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-27T14:57:48', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'da39638e-6d3f-4ed8-95cb-90517fdc07c0' User entered 'None (0)'	System	27 Sep 2020 18:58:08
	System	27 Sep 2020 18:58:08

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-27T14:57:50', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'da39638e-6d3f-4ed8-95cb-90517fdc07c0' User entered 'None (0)'	System	27 Sep 2020 18:58:08
	System	27 Sep 2020 18:58:08

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-27T14:58:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'da39638e-6d3f-4ed8-95cb-90517fdc07c0'	System	27 Sep 2020 18:58:08
User entered 'No (N)'	System	27 Sep 2020 18:58:08

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-27T14:58:03', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'da39638e-6d3f-4ed8-95cb-90517fdc07c0' User entered '27 Sep 2020 14:58'	System	27 Sep 2020 18:58:08
	System	27 Sep 2020 18:58:08

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	24 Sep 2020 14:53:16
User entered 'Day 5'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-28T13:28:51', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'a0dd266b-ad6b-4b1c-948e-63e5b28f9daa' User entered 'None (0)'	System	28 Sep 2020 17:29:09
	System	28 Sep 2020 17:29:09

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-28T13:28:53', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'a0dd266b-ad6b-4b1c-948e-63e5b28f9daa' User entered 'None (0)'	System	28 Sep 2020 17:29:09
	System	28 Sep 2020 17:29:09

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-28T13:28:55', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'a0dd266b-ad6b-4b1c-948e-63e5b28f9daa' User entered 'None (0)'	System	28 Sep 2020 17:29:09
	System	28 Sep 2020 17:29:09

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-28T13:28:57', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'a0dd266b-ad6b-4b1c-948e-63e5b28f9daa' User entered 'None (0)'	System	28 Sep 2020 17:29:09
	System	28 Sep 2020 17:29:09

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-28T13:28:59', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'a0dd266b-ad6b-4b1c-948e-63e5b28f9daa' User entered 'None (0)'	System	28 Sep 2020 17:29:09
	System	28 Sep 2020 17:29:09

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-28T13:29:01', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'a0dd266b-ad6b-4b1c-948e-63e5b28f9daa' User entered 'None (0)'	System	28 Sep 2020 17:29:09
	System	28 Sep 2020 17:29:09

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-28T13:29:04', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'a0dd266b-ad6b-4b1c-948e-63e5b28f9daa'	System	28 Sep 2020 17:29:09
User entered 'No (N)'	System	28 Sep 2020 17:29:09

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-28T13:29:06', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'a0dd266b-ad6b-4b1c-948e-63e5b28f9daa' User entered '28 Sep 2020 13:29'	System	28 Sep 2020 17:29:09
	System	28 Sep 2020 17:29:09

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	24 Sep 2020 14:53:16
User entered 'Day 6'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-29T12:03:38', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'eab6c8de-2990-4087-83fa-0a87f54eb498' User entered 'None (0)'	System	29 Sep 2020 16:04:13
	System	29 Sep 2020 16:04:13

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-29T12:03:40', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'eab6c8de-2990-4087-83fa-0a87f54eb498' User entered 'None (0)'	System	29 Sep 2020 16:04:13
	System	29 Sep 2020 16:04:13

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-29T12:03:42', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'eab6c8de-2990-4087-83fa-0a87f54eb498' User entered 'None (0)'	System	29 Sep 2020 16:04:13
	System	29 Sep 2020 16:04:13

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-29T12:03:44', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'eab6c8de-2990-4087-83fa-0a87f54eb498' User entered 'None (0)'	System	29 Sep 2020 16:04:13
	System	29 Sep 2020 16:04:13

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-29T12:03:46', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'eab6c8de-2990-4087-83fa-0a87f54eb498' User entered 'None (0)'	System	29 Sep 2020 16:04:13
	System	29 Sep 2020 16:04:13

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-29T12:03:47', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'eab6c8de-2990-4087-83fa-0a87f54eb498'	System	29 Sep 2020 16:04:13
User entered 'None (0)'	System	29 Sep 2020 16:04:13

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-29T12:03:50', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'eab6c8de-2990-4087-83fa-0a87f54eb498'	System	29 Sep 2020 16:04:13
User entered 'No (N)'	System	29 Sep 2020 16:04:13

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-29T12:03:52', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'eab6c8de-2990-4087-83fa-0a87f54eb498' User entered '29 Sep 2020 12:03'	System	29 Sep 2020 16:04:13
	System	29 Sep 2020 16:04:13

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	24 Sep 2020 14:53:16
User entered 'Day 7'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-30T13:44:11', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '99db5872-5eb6-4ce3-b019-1abccde79e16' User entered 'None (0)'	System	30 Sep 2020 17:45:25
	System	30 Sep 2020 17:45:25

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-30T13:44:15', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '99db5872-5eb6-4ce3-b019-1abccde79e16' User entered 'None (0)'	System	30 Sep 2020 17:45:25
	System	30 Sep 2020 17:45:25

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-30T13:44:21', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '99db5872-5eb6-4ce3-b019-1abccde79e16' User entered 'None (0)'	System	30 Sep 2020 17:45:25
	System	30 Sep 2020 17:45:25

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-30T13:44:23', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '99db5872-5eb6-4ce3-b019-1abccde79e16' User entered 'None (0)'	System	30 Sep 2020 17:45:25
	System	30 Sep 2020 17:45:25

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-30T13:44:25', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '99db5872-5eb6-4ce3-b019-1abccde79e16' User entered 'None (0)'	System	30 Sep 2020 17:45:25
	System	30 Sep 2020 17:45:25

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-30T13:44:26', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '99db5872-5eb6-4ce3-b019-1abccde79e16' User entered 'None (0)'	System	30 Sep 2020 17:45:25
	System	30 Sep 2020 17:45:25

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:08

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 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-30T13:44:30', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '99db5872-5eb6-4ce3-b019-1abccde79e16' User entered 'No (N)'	System	30 Sep 2020 17:45:25
	System	30 Sep 2020 17:45:25

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-09-30T13:44:32', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '99db5872-5eb6-4ce3-b019-1abccde79e16' User entered '30 Sep 2020 13:44'	System	30 Sep 2020 17:45:25
	System	30 Sep 2020 17:45:25

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 14:53:16

US3542030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 14:53:16

US3542030

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	03 Oct 2020 15:26:49
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 20:02:33

US3542030

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	03 Oct 2020 15:26:49
User entered '1 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 20:02:33

US3542030

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	03 Oct 2020 15:26:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 20:02:33

US3542030

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	03 Oct 2020 15:26:49
User entered empty.	(b) (4) Erika Faust (b) (4)	02 Oct 2020 20:02:33

US3542030

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	03 Oct 2020 15:26:49
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 20:02:37

US3542030

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered 'I'	System	02 Oct 2020 20:02:37

US3542030

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	21 Oct 2020 18:29:42
User entered 'No (N)'	(b) (4) Erika Faust (b) (4)	16 Oct 2020 18:57:14

US3542030

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	21 Oct 2020 18:29:42
User entered empty.	(b) (4) Erika Faust (b) (4)	16 Oct 2020 18:57:14

US3542030

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4) (b) (4)	21 Oct 2020 18:29:42
User entered empty.	Erika Faust (b) (4) (b) (4)	16 Oct 2020 18:57:14

US3542030

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	21 Oct 2020 18:29:42
User entered empty.	(b) (4) Erika Faust (b) (4)	16 Oct 2020 18:57:14

US3542030

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	21 Oct 2020 18:29:42
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	16 Oct 2020 18:54:11

US3542030

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered 'l'	System	16 Oct 2020 18:54:11

US3542030

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	21 Oct 2020 18:29:42
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	16 Oct 2020 18:54:23

US3542030

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	21 Oct 2020 18:29:42
User entered '15 Oct 2020'	(b) (4) Erika Faust (b) (4)	16 Oct 2020 18:54:23

US3542030

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	21 Oct 2020 18:29:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4)	16 Oct 2020 18:54:23

US3542030

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	21 Oct 2020 18:29:42
User entered empty.	(b) (4) Erika Faust (b) (4)	16 Oct 2020 18:54:23

US3542030

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	21 Oct 2020 18:29:42
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	16 Oct 2020 18:54:27

US3542030

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered 'l'	System	16 Oct 2020 18:54:27

US3542030

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:24:14
User signature succeeded.	David Diemert (u) (4)	23 Oct 2020 13:45:37
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:23:50

US3542030

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:24:14
User signature succeeded.	David Diemert (u) (4)	23 Oct 2020 13:45:37
User entered '22 Oct 2020'	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:23:50
	(b) (4)	

US3542030

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:24:14
User signature succeeded.	David Diemert (u) (4)	23 Oct 2020 13:45:37
User entered 'Clinic (Clinic)'	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:23:50

US3542030

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:24:14
User entered 'VISIT3'	System	22 Oct 2020 16:23:50

US3542030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:24:14
User signature succeeded.	David Diemert (u) (4)	23 Oct 2020 13:45:48
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:24:58

US3542030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:24:14
User signature succeeded.	David Diemert (u) (4)	23 Oct 2020 13:45:48
User entered '22 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:24:58

US3542030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:24:14
User signature succeeded.	David Diemert (u) (4)	23 Oct 2020 13:45:48
User entered '09:15'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:24:58

US3542030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:24:14
User entered '22 Oct 2020 09:15'	System	22 Oct 2020 16:24:58

US3542030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:24:14
User signature succeeded.	David Diemert (u) (4)	23 Oct 2020 13:45:48
User entered '98.0' F	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:24:58

US3542030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:24:14
User signature succeeded.	David Diemert (u) (4)	23 Oct 2020 13:45:48
User entered 'Oral (Oral)'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:24:58

US3542030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:24:14
User signature succeeded.	David Diemert (u) (4)	23 Oct 2020 13:45:48
User entered empty.	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:24:58

US3542030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:24:14
User signature succeeded.	David Diemert (u) (4)	23 Oct 2020 13:45:48
User entered '84'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:24:58

US3542030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:24:14
User entered 'bpm'	System	22 Oct 2020 16:24:58

US3542030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:24:14
User signature succeeded.	David Diemert (u) (4)	23 Oct 2020 13:45:48
User entered '16'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:24:58

US3542030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:24:14
User entered 'breaths/min'	System	22 Oct 2020 16:24:58

US3542030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:24:14
User signature succeeded.	David Diemert (u) (4)	23 Oct 2020 13:45:48
User entered '131'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:24:58

US3542030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:24:14
User entered 'mmHg'	System	22 Oct 2020 16:24:58

US3542030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:24:14
User signature succeeded.	David Diemert (u) (4)	23 Oct 2020 13:45:48
User entered '85'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:24:58

US3542030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:24:14
User entered 'mmHg'	System	22 Oct 2020 16:24:58

US3542030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:24:14

US3542030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:24:14

US3542030

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:24:14
User signature succeeded.	David Diemert (u) (4)	23 Oct 2020 13:45:37
User entered 'No (N)'	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:23:56

US3542030

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:24:14
User signature succeeded.	David Diemert (u) (4)	23 Oct 2020 13:45:37
User entered empty.	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:23:56

US3542030

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:24:14
User signature succeeded.	David Diemert (u) (4)	23 Oct 2020 13:45:37
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:24:08

US3542030

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:24:14
User signature succeeded.	David Diemert (u) (4)	23 Oct 2020 13:45:37
User entered '22 Oct 2020'	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:24:08

US3542030

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:24:14
User signature succeeded.	David Diemert (u) (4)	23 Oct 2020 13:45:37
User entered '09:30'	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:24:08

US3542030

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:08

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:24:14
User entered '22 Oct 2020 09:30'	System	22 Oct 2020 16:24:08

US3542030

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	23 Oct 2020 13:45:37
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:24:15

US3542030

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered 'l'	System	22 Oct 2020 16:24:15

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	20 Aug 2020 17:08:56
User entered 'Day 64'	System	20 Aug 2020 17:08:56

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-10-20T07:02:14', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '377979d8-a343-4224-935d-708f7e5db0a1'	System	20 Oct 2020 11:02:49
User entered 'Yes (Y)'	System	20 Oct 2020 11:02:49

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-10-20T07:02:18', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '377979d8-a343-4224-935d-708f7e5db0a1'	System	20 Oct 2020 11:02:49
User entered 'No (N)'	System	20 Oct 2020 11:02:49

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-10-20T07:02:23', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '377979d8-a343-4224-935d-708f7e5db0a1'	System	20 Oct 2020 11:02:49
User entered 'No (N)'	System	20 Oct 2020 11:02:49

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-10-20T07:02:31', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '377979d8-a343-4224-935d-708f7e5db0a1'	System	20 Oct 2020 11:02:49
User entered 'No (N)'	System	20 Oct 2020 11:02:49

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-10-20T07:02:45', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '377979d8-a343-4224-935d-708f7e5db0a1' User entered '20 Oct 2020 07:02:45'	System	20 Oct 2020 11:02:49
	System	20 Oct 2020 11:02:49

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	20 Aug 2020 17:08:56
User entered '20 Oct 2020 00:01'	System	20 Aug 2020 17:08:56

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	20 Aug 2020 17:08:56
User entered '24 Oct 2020 23:59'	System	20 Aug 2020 17:08:56

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	20 Aug 2020 17:08:56
User entered 'Day 71'	System	20 Aug 2020 17:08:56

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-10-29T09:12:08', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'b4998e6e-88fc-4a73-9a30-9a58078b1be5'	System	29 Oct 2020 13:12:18
User entered 'No (N)'	System	29 Oct 2020 13:12:18

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-10-29T09:12:13', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'b4998e6e-88fc-4a73-9a30-9a58078b1be5'	System	29 Oct 2020 13:12:18
User entered 'No (N)'	System	29 Oct 2020 13:12:18

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-10-29T09:12:16', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'b4998e6e-88fc-4a73-9a30-9a58078b1be5' User entered '29 Oct 2020 09:12:16'	System	29 Oct 2020 13:12:18
	System	29 Oct 2020 13:12:18

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	20 Aug 2020 17:08:56
User entered '27 Oct 2020 00:01'	System	20 Aug 2020 17:08:56

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	20 Aug 2020 17:08:56
User entered '31 Oct 2020 23:59'	System	20 Aug 2020 17:08:56

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	20 Aug 2020 17:08:56
User entered 'Day 78'	System	20 Aug 2020 17:08:56

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-11-05T15:26:42', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '4ae0f057-e27e-4e31-afab-ecf8431a1ab8'	System	05 Nov 2020 20:26:53
User entered 'No (N)'	System	05 Nov 2020 20:26:53

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-11-05T15:26:49', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '4ae0f057-e27e-4e31-afab-ecf8431a1ab8'	System	05 Nov 2020 20:26:53
User entered 'No (N)'	System	05 Nov 2020 20:26:53

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-11-05T15:26:52', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '4ae0f057-e27e-4e31-afab-ecf8431a1ab8' User entered '05 Nov 2020 15:26:52'	System	05 Nov 2020 20:26:53
	System	05 Nov 2020 20:26:53

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	20 Aug 2020 17:08:56
User entered '03 Nov 2020 00:01'	System	20 Aug 2020 17:08:56

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:32
Data entry locked.	System	20 Aug 2020 17:08:56
User entered '07 Nov 2020 23:59'	System	20 Aug 2020 17:08:56

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:46:05
Data entry locked.	System	20 Aug 2020 17:08:56
User entered 'Day 92'	System	20 Aug 2020 17:08:56

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:46:05

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:46:05

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:46:05

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:46:05

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

Fever (Temperature $\geq$ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:46:05

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:46:05

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:46:05

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:46:05

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:46:05

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:46:05

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:46:05

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:46:05

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:46:05

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:46:05

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:46:05

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:46:05

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:46:05

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:46:05

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:46:05

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:46:05

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:46:05

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:46:05

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:46:05

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:46:05

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:46:05

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:46:05
Data entry locked.	System	20 Aug 2020 17:08:56
User entered '17 Nov 2020 00:01'	System	20 Aug 2020 17:08:56

US3542030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:46:05
Data entry locked.	System	20 Aug 2020 17:08:56
User entered '21 Nov 2020 23:59'	System	20 Aug 2020 17:08:56

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-11-21T15:02:11', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'c9a12f6a-5c0c-4151-9294-ae2e3208138d' User entered 'No (N)'	System	21 Nov 2020 20:02:26
	System	21 Nov 2020 20:02:26

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-11-21T15:02:16', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'c9a12f6a-5c0c-4151-9294-ae2e3208138d' User entered 'No (N)'	System	21 Nov 2020 20:02:26

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-11-21T15:02:23', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'c9a12f6a-5c0c-4151-9294-ae2e3208138d' User entered '21 Nov 2020 15:02:23'	System	21 Nov 2020 20:02:26
	System	21 Nov 2020 20:02:26

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-11-29T23:50:16', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '764626fe-0db5-4002-bb57-b0e3cda997ea' User entered 'No (N)'	System	30 Nov 2020 04:50:34

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-11-29T23:50:25', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '764626fe-0db5-4002-bb57-b0e3cda997ea' User entered 'No (N)'	System	30 Nov 2020 04:50:34
	System	30 Nov 2020 04:50:34

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-11-29T23:50:28', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '764626fe-0db5-4002-bb57-b0e3cda997ea' User entered '29 Nov 2020 23:50:28'	System	30 Nov 2020 04:50:34

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-12-05T07:46:01', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'cf3109fd-e60b-4ddc-910a-e8dfddc3349a' User entered 'No (N)'	System	05 Dec 2020 12:46:16
	System	05 Dec 2020 12:46:16

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-12-05T07:46:10', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'cf3109fd-e60b-4ddc-910a-e8dfddc3349a' User entered 'No (N)'	System	05 Dec 2020 12:46:16
	System	05 Dec 2020 12:46:16

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-12-05T07:46:13', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'cf3109fd-e60b-4ddc-910a-e8dfddc3349a' User entered '05 Dec 2020 07:46:13'	System	05 Dec 2020 12:46:16
	System	05 Dec 2020 12:46:16

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-12-14T12:12:17', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '664991ff-f751-4967-b8b2-7abc15cd64d7'	System	14 Dec 2020 17:12:27
User entered 'No (N)'	System	14 Dec 2020 17:12:27

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-12-14T12:12:21', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '664991ff-f751-4967-b8b2-7abc15cd64d7'	System	14 Dec 2020 17:12:27
User entered 'No (N)'	System	14 Dec 2020 17:12:27

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-12-14T12:12:24', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '664991ff-f751-4967-b8b2-7abc15cd64d7' User entered '14 Dec 2020 12:12:24'	System	14 Dec 2020 17:12:27
	System	14 Dec 2020 17:12:27

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-12-21T09:51:19', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '4b560d79-fdea-4fc9-86e4-db0857a5d877'	System	21 Dec 2020 14:51:30
User entered 'No (N)'	System	21 Dec 2020 14:51:30

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-12-21T09:51:25', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '4b560d79-fdea-4fc9-86e4-db0857a5d877'	System	21 Dec 2020 14:51:30
User entered 'No (N)'	System	21 Dec 2020 14:51:30

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-12-21T09:51:27', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '4b560d79-fdea-4fc9-86e4-db0857a5d877'	System	21 Dec 2020 14:51:30
User entered '21 Dec 2020 09:51:27'	System	21 Dec 2020 14:51:30

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-12-28T12:25:25', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '12c2727d-c23b-4c71-b444-c734e518790c' User entered 'No (N)'	System	28 Dec 2020 17:25:35
	System	28 Dec 2020 17:25:35

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-12-28T12:25:30', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '12c2727d-c23b-4c71-b444-c734e518790c' User entered 'No (N)'	System	28 Dec 2020 17:25:35
	System	28 Dec 2020 17:25:35

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2020-12-28T12:25:33', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '12c2727d-c23b-4c71-b444-c734e518790c' User entered '28 Dec 2020 12:25:33'	System	28 Dec 2020 17:25:35
	System	28 Dec 2020 17:25:35

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-01-04T13:18:04', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '433dc8f5-8df5-417b-ac36-529e34a9050a' User entered 'No (N)'	System	04 Jan 2021 18:18:14

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-01-04T13:18:08', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '433dc8f5-8df5-417b-ac36-529e34a9050a' User entered 'No (N)'	System	04 Jan 2021 18:18:14

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-01-04T13:18:11', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '433dc8f5-8df5-417b-ac36-529e34a9050a' User entered '04 Jan 2021 13:18:11'	System	04 Jan 2021 18:18:14
	System	04 Jan 2021 18:18:14

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-01-09T16:23:14', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '585d601c-ce40-48bd-9de9-1e27232eb8ea' User entered 'No (N)'	System	09 Jan 2021 21:23:23
	System	09 Jan 2021 21:23:23

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-01-09T16:23:18', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '585d601c-ce40-48bd-9de9-1e27232eb8ea' User entered 'No (N)'	System	09 Jan 2021 21:23:23

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-01-09T16:23:22', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '585d601c-ce40-48bd-9de9-1e27232eb8ea' User entered '09 Jan 2021 16:23:22'	System	09 Jan 2021 21:23:23
	System	09 Jan 2021 21:23:23

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-01-16T22:30:02', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'f1769b96-48d6-4b92-a904-eb638685408'	System	17 Jan 2021 03:30:17
User entered 'No (N)'	System	17 Jan 2021 03:30:17

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-01-16T22:30:09', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'f1769b96-48d6-4b92-a904-ebe638685408' User entered 'No (N)'	System	17 Jan 2021 03:30:17

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-01-16T22:30:12', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'f1769b96-48d6-4b92-a904-cbe638685408' User entered '16 Jan 2021 22:30:12'	System	17 Jan 2021 03:30:17
	System	17 Jan 2021 03:30:17

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-01-23T23:44:13', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'bd046f1a-bfd1-40ca-8e65-49405bee33d0'	System	24 Jan 2021 04:44:30
User entered 'No (N)'	System	24 Jan 2021 04:44:30

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-01-23T23:44:16', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'bd046f1a-bfd1-40ca-8e65-49405bee33d0'	System	24 Jan 2021 04:44:30
User entered 'No (N)'	System	24 Jan 2021 04:44:30

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-01-23T23:44:28', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'bd046f1a-bfd1-40ca-8e65-49405bee33d0' User entered '23 Jan 2021 23:44:28'	System	24 Jan 2021 04:44:30
	System	24 Jan 2021 04:44:30

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-02-01T12:00:33', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'f1155095-edaa-491a-8978-77173c96a3a4' User entered 'No (N)'	System	01 Feb 2021 17:02:34

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-02-01T12:00:39', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'f1155095-edaa-491a-8978-77173c96a3a4' User entered 'No (N)'	System	01 Feb 2021 17:02:34

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-02-01T12:00:42', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'f1155095-edaa-491a-8978-77173c96a3a4' User entered '01 Feb 2021 12:00:42'	System	01 Feb 2021 17:02:34
	System	01 Feb 2021 17:02:34

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-02-09T18:08:53', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '4b51d728-a892-48de-b577-39cefe618967' User entered 'No (N)'	System	09 Feb 2021 23:12:43
	System	09 Feb 2021 23:12:43

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-02-09T18:08:29', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '4b51d728-a892-48de-b577-39cefe618967'	System	09 Feb 2021 23:12:43
User entered 'No (N)'	System	09 Feb 2021 23:12:43

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-02-09T18:08:57', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '4b51d728-a892-48de-b577-39cefe618967' User entered '09 Feb 2021 18:08:57'	System	09 Feb 2021 23:12:43
	System	09 Feb 2021 23:12:43

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-02-15T13:14:11', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'f5b94fc9-65af-48c9-b5a4-95be5a82ee7d' User entered 'No (N)'	System	15 Feb 2021 18:14:41

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-02-15T13:14:16', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'f5b94fc9-65af-48c9-b5a4-95be5a82ee7d' User entered 'No (N)'	System	15 Feb 2021 18:14:41

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-02-15T13:14:19', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'f5b94fc9-65af-48c9-b5a4-95be5a82ee7d' User entered '15 Feb 2021 13:14:19'	System	15 Feb 2021 18:14:41
	System	15 Feb 2021 18:14:41

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-02-20T08:23:22', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '6d8325cb-fdd6-4ab6-9e89-ee54493c119b' User entered 'Yes (Y)'	System	20 Feb 2021 13:23:50
	System	20 Feb 2021 13:23:50

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-02-20T08:23:26', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '6d8325cb-fdd6-4ab6-9e89-ee54493c119b' User entered 'No (N)'	System	20 Feb 2021 13:23:50
	System	20 Feb 2021 13:23:50

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-02-20T08:23:32', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '6d8325cb-fdd6-4ab6-9e89-ee54493c119b' User entered 'No (N)'	System	20 Feb 2021 13:23:50
	System	20 Feb 2021 13:23:50

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-02-20T08:23:38', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '6d8325cb-fdd6-4ab6-9e89-ee54493c119b' User entered 'No (N)'	System	20 Feb 2021 13:23:50
	System	20 Feb 2021 13:23:50

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-02-20T08:23:48', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '6d8325cb-fdd6-4ab6-9e89-ee54493c119b' User entered '20 Feb 2021 08:23:48'	System	20 Feb 2021 13:23:50
	System	20 Feb 2021 13:23:50

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-03-01T12:01:28-05:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'b06cce88-91b8-464a-b42e-ccee9cb1431b'	System	01 Mar 2021 17:08:38
User entered 'No (N)'	System	01 Mar 2021 17:08:38

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-03-01T12:01:33-05:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'b06cce88-91b8-464a-b42e-ccee9cb1431b'	System	01 Mar 2021 17:08:38
User entered 'No (N)'	System	01 Mar 2021 17:08:38

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-03-01T12:01:36-05:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'b06cce88-91b8-464a-b42e-ccee9cb1431b' User entered '01 Mar 2021 12:01:36'	System	01 Mar 2021 17:08:38
	System	01 Mar 2021 17:08:38

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-03-07T22:10:04-05:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '22f2153d-1d70-4829-8ccf-d845b0d51a86'	System	08 Mar 2021 03:14:10
User entered 'Yes (Y)'	System	08 Mar 2021 03:14:10

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-03-07T22:10:09-05:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '22f2153d-1d70-4829-8ccf-d845b0d51a86'	System	08 Mar 2021 03:14:10
User entered 'No (N)'	System	08 Mar 2021 03:14:10

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-03-07T22:10:20-05:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '22f2153d-1d70-4829-8ccf-d845b0d51a86'	System	08 Mar 2021 03:14:10
User entered 'No (N)'	System	08 Mar 2021 03:14:10

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-03-07T22:10:24-05:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '22f2153d-1d70-4829-8ccf-d845b0d51a86'	System	08 Mar 2021 03:14:10
User entered 'Yes (Y)'	System	08 Mar 2021 03:14:10

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-03-07T22:10:33-05:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '22f2153d-1d70-4829-8ccf-d845b0d51a86'	System	08 Mar 2021 03:14:10
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Mar 2021 03:14:10

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-03-07T22:10:37-05:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '22f2153d-1d70-4829-8ccf-d845b0d51a86'	System	08 Mar 2021 03:14:10
User entered '07 Mar 2021 22:10:37'	System	08 Mar 2021 03:14:10

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-03-16T18:17:46-04:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '1b28922b-0e2f-4baf-9bf8-a1682764cab4'	System	16 Mar 2021 22:19:43
User entered 'No (N)'	System	16 Mar 2021 22:19:43

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-03-16T18:17:51-04:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '1b28922b-0e2f-4baf-9bf8-a1682764cab4'	System	16 Mar 2021 22:19:43
User entered 'No (N)'	System	16 Mar 2021 22:19:43

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-03-16T18:17:54-04:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '1b28922b-0e2f-4baf-9bf8-a1682764cab4'	System	16 Mar 2021 22:19:43
User entered '16 Mar 2021 18:17:54'	System	16 Mar 2021 22:19:43

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-03-21T09:17:09-04:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '4acba3fd-9f36-40c1-ab7d-33564cbe4022'	System	21 Mar 2021 13:17:19
User entered 'No (N)'	System	21 Mar 2021 13:17:19

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-03-21T09:17:12-04:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '4acba3fd-9f36-40c1-ab7d-33564cbe4022'	System	21 Mar 2021 13:17:19
User entered 'No (N)'	System	21 Mar 2021 13:17:19

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-03-21T09:17:15-04:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '4acba3fd-9f36-40c1-ab7d-33564cbe4022'	System	21 Mar 2021 13:17:19
User entered '21 Mar 2021 09:17:15'	System	21 Mar 2021 13:17:19

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-03-29T07:09:19-04:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '64f71f1b-cd00-4a61-bb01-7dfed72a037f' User entered 'No (N)'	System	29 Mar 2021 11:09:36
	System	29 Mar 2021 11:09:36

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-03-29T07:09:29-04:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '64f71f1b-cd00-4a61-bb01-7dfed72a037f' User entered 'No (N)'	System	29 Mar 2021 11:09:36
	System	29 Mar 2021 11:09:36

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-03-29T07:09:32-04:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '64f71f1b-cd00-4a61-bb01-7dfed72a037f' User entered '29 Mar 2021 07:09:32'	System	29 Mar 2021 11:09:36
	System	29 Mar 2021 11:09:36

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-04-10T09:07:03-04:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '2525819c-cf31-42e4-a8b7-d15ff3a5e285'	System	10 Apr 2021 13:07:23
User entered 'No (N)'	System	10 Apr 2021 13:07:23

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-04-10T09:07:13-04:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '2525819c-cf31-42e4-a8b7-d15ff3a5e285'	System	10 Apr 2021 13:07:23
User entered 'No (N)'	System	10 Apr 2021 13:07:23

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-04-10T09:07:19-04:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '2525819c-cf31-42e4-a8b7-d15ff3a5e285'	System	10 Apr 2021 13:07:23
User entered '10 Apr 2021 09:07:19'	System	10 Apr 2021 13:07:23

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-04-19T09:17:22-04:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '8cf14293-c32a-419b-90fb-c57c9101435a'	System	19 Apr 2021 13:17:37
User entered 'No (N)'	System	19 Apr 2021 13:17:37

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-04-19T09:17:26-04:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '8cf14293-c32a-419b-90fb-c57c9101435a' User entered 'No (N)'	System	19 Apr 2021 13:17:37

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-04-19T09:17:29-04:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '8cf14293-c32a-419b-90fb-c57c9101435a' User entered '19 Apr 2021 09:17:29'	System	19 Apr 2021 13:17:37
	System	19 Apr 2021 13:17:37

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-04-26T12:00:19-04:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'e2026569-6245-43ca-80a3-cedd305564c6'	System	26 Apr 2021 16:02:28
User entered 'Yes (Y)'	System	26 Apr 2021 16:02:28

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-04-26T12:00:21-04:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'e2026569-6245-43ca-80a3-cedd305564c6'	System	26 Apr 2021 16:02:28
User entered 'No (N)'	System	26 Apr 2021 16:02:28

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-04-26T12:00:28-04:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'e2026569-6245-43ca-80a3-cedd305564c6'	System	26 Apr 2021 16:02:28
User entered 'No (N)'	System	26 Apr 2021 16:02:28

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-04-26T12:00:36-04:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'e2026569-6245-43ca-80a3-cedd305564c6'	System	26 Apr 2021 16:02:28
User entered 'Yes (Y)'	System	26 Apr 2021 16:02:28

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-04-26T12:00:41-04:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'e2026569-6245-43ca-80a3-cedd305564c6'	System	26 Apr 2021 16:02:28
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Apr 2021 16:02:28

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-04-26T12:00:43-04:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: 'e2026569-6245-43ca-80a3-cedd305564c6'	System	26 Apr 2021 16:02:28
User entered '26 Apr 2021 12:00:43'	System	26 Apr 2021 16:02:28

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-05-01T08:59:27-04:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '56ddffdd-d3f4-4a4c-9bac-9de81957a040'	System	01 May 2021 12:59:36
User entered 'No (N)'	System	01 May 2021 12:59:36

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-05-01T08:59:30-04:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '56ddffdd-d3f4-4a4c-9bac-9de81957a040'	System	01 May 2021 12:59:36
User entered 'No (N)'	System	01 May 2021 12:59:36

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-05-01T08:59:33-04:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '56ddffdd-d3f4-4a4c-9bac-9de81957a040'	System	01 May 2021 12:59:36
User entered '01 May 2021 08:59:33'	System	01 May 2021 12:59:36

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '22 Oct 2022 00:01'	System	19 Nov 2020 23:46:05

US3542030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:05
Amendment Manager: User entered '26 Oct 2022 23:59'	System	19 Nov 2020 23:46:05

US3542030

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:12:08

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-03-01T12:00:56-05:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '1526766a-bbeb-43b7-aab0-568739e43ae6'	System	01 Mar 2021 17:04:47
User entered 'No (N)'	System	01 Mar 2021 17:04:47

US3542030

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:12:08

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CC45F01A-87BC-494A-89EA-FD36151E281A)', Time: '2021-03-01T12:00:59-05:00', User OID: 'PatientReportedOutcome (US3542030)', ODM File OID: '1526766a-bbeb-43b7-aab0-568739e43ae6' User entered '01 Mar 2021 12:00:59'	System	01 Mar 2021 17:04:47
	System	01 Mar 2021 17:04:47

US3542030

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	20 Nov 2020 04:10:06
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	17 Nov 2020 18:34:03

US3542030

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	20 Nov 2020 04:10:06
User entered '16 Nov 2020'	(b) (4) DeEnna Wedding (b) (4)	17 Nov 2020 18:34:03

US3542030

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	20 Nov 2020 04:10:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) DeEnna Wedding (b) (4)	17 Nov 2020 18:34:03

US3542030

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	20 Nov 2020 04:10:06
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	17 Nov 2020 18:34:03
	(b) (4)	

US3542030

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User signature succeeded.	David Diemert (u) (4)	20 Nov 2020 04:10:06
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	17 Nov 2020 18:34:31
	(b) (4)	

US3542030

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:23:56
User entered 'l'	System	17 Nov 2020 18:34:31

US3542030

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:57:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Dec 2020 16:39:43

US3542030

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:57:30
User entered '21 Dec 2020'	(b) (4), (b) (6)	22 Dec 2020 16:39:43

US3542030

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:57:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Dec 2020 16:39:43

US3542030

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:57:30
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:39:43

US3542030

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:57:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Dec 2020 16:39:51

US3542030

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User entered 'I'	System	22 Dec 2020 16:39:51

US3542030

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:03
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Jan 2021 18:06:42

US3542030

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:03
User entered '19 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Jan 2021 18:06:42

US3542030

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4)	22 Jan 2021 18:06:42

US3542030

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:03
User entered empty.	(b) (4) Erika Faust (b) (4)	22 Jan 2021 18:06:42

US3542030

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:03
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Jan 2021 18:06:34

US3542030

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User entered 'l'	System	22 Jan 2021 18:06:34

US3542030

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User signature succeeded.	David Diemert (b) (4)	23 Feb 2021 20:11:07
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	23 Feb 2021 18:10:45

US3542030

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User signature succeeded.	David Diemert (b) (4)	23 Feb 2021 20:11:07
User entered '22 Feb 2021'	(b) (4) Taylor Ladson (b) (4)	23 Feb 2021 18:10:45

US3542030

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User signature succeeded.	David Diemert (b) (4)	23 Feb 2021 20:11:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Taylor Ladson (b) (4)	23 Feb 2021 18:10:45

US3542030

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User signature succeeded.	David Diemert (b) (4)	23 Feb 2021 20:11:07
User entered empty.	(b) (4) Taylor Ladson (b) (4)	23 Feb 2021 18:10:45

US3542030

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User signature succeeded.	David Diemert (b) (4)	23 Feb 2021 20:11:07
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	23 Feb 2021 18:10:35

US3542030

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User entered 'l'	System	23 Feb 2021 18:10:35

US3542030

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User signature succeeded.	David Diemert (b) (4)	26 Mar 2021 16:51:18
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 18:00:30

US3542030

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User signature succeeded.	David Diemert (b) (4)	26 Mar 2021 16:51:18
User entered '25 Mar 2021'	(b) (4) Erika Faust (b) (4)	25 Mar 2021 18:00:30

US3542030

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User signature succeeded.	David Diemert (b) (4)	26 Mar 2021 16:51:18
User entered 'Clinic (Clinic)'	(b) (4) Erika Faust (b) (4)	25 Mar 2021 18:00:30

US3542030

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User entered 'VISIT4'	System	25 Mar 2021 18:00:30

US3542030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:12:57
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	31 Mar 2021 14:21:08

US3542030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:12:57
User entered empty.	(b) (4) Erika Faust (b) (4)	31 Mar 2021 14:21:08

US3542030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:12:57
User entered empty.	(b) (4) Erika Faust (b) (4)	31 Mar 2021 14:21:08

US3542030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User entered empty.	System	31 Mar 2021 14:21:08

US3542030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:12:57
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	31 Mar 2021 14:21:08

US3542030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:12:57
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	31 Mar 2021 14:21:08

US3542030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:12:57
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	31 Mar 2021 14:21:08

US3542030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:12:57
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	31 Mar 2021 14:21:08

US3542030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User entered empty.	System	31 Mar 2021 14:21:08

US3542030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:12:57
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	31 Mar 2021 14:21:08

US3542030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User entered empty.	System	31 Mar 2021 14:21:08

US3542030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:12:57
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	31 Mar 2021 14:21:08

US3542030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User entered empty.	System	31 Mar 2021 14:21:08

US3542030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:12:57
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	31 Mar 2021 14:21:08

US3542030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User entered empty.	System	31 Mar 2021 14:21:08

US3542030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16

US3542030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16

US3542030

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User signature succeeded.	David Diemert (b) (4)	26 Mar 2021 16:51:18
User entered 'No (N)'	(b) (4) Erika Faust (b) (4)	25 Mar 2021 18:00:41

US3542030

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User signature succeeded.	David Diemert (b) (4)	26 Mar 2021 16:51:18
User entered empty.	(b) (4) Erika Faust (b) (4)	25 Mar 2021 18:00:41

US3542030

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User signature succeeded.	David Diemert (b) (4)	26 Mar 2021 16:51:18
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	25 Mar 2021 18:00:52

US3542030

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User signature succeeded.	David Diemert (b) (4)	26 Mar 2021 16:51:18
User entered '25 Mar 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 18:00:52

US3542030

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:08

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User signature succeeded.	David Diemert (b) (4)	26 Mar 2021 16:51:18
User entered '09:29'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Mar 2021 18:00:52

US3542030

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:08

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User entered '25 Mar 2021 09:29'	System	25 Mar 2021 18:00:52

US3542030

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User signature succeeded.	David Diemert (b) (4)	26 Mar 2021 16:51:18
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	25 Mar 2021 18:00:57

US3542030

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:16
User entered 'I'	System	25 Mar 2021 18:00:57

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:12:08

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:07
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered '08 Dec 2020'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:49:32

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:12:08

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:07
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered '08:45'	(b) (4) Erika Faust (b) (4) (b) (4)	10 Dec 2020 15:49:32

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:12:08

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:07
User entered '08 Dec 2020 08:45'	System	10 Dec 2020 15:49:32

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:12:08

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:07
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Safety Call (Safety Call)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:49:32

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:12:08

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:07
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:49:32

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Day 1 (Day 1)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:53:48

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered '07 Dec 2020'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:53:48

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	10 Dec 2020 15:53:48

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User closed query 'Per CDM: It appears that O2 saturation and temperature were not provided for days 1 and 2. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 05:24:32
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:10
Query 'Per CDM: It appears that O2 saturation and temperature were not provided for days 1 and 2. If not collected, please consider recording as Not Done.' answered with 'Updated accordingly' (Site from DM).	Hannah Yellin (b) (4)	13 Jan 2021 19:17:43
Signature has been broken.	Hannah Yellin (b) (4)	13 Jan 2021 19:17:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Hannah Yellin (b) (4)	13 Jan 2021 19:17:35
User opened query 'Per CDM: It appears that O2 saturation and temperature were not provided for days 1 and 2. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 18:55:07
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered empty.	Erika Faust (b) (4)	10 Dec 2020 15:53:48

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User entered '%'	System	13 Jan 2021 19:17:35
User entered empty.	System	10 Dec 2020 15:53:48

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:10
Signature has been broken.	(b) (4)	
	Hannah Yellin (b) (4)	13 Jan 2021 19:17:35
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Hannah Yellin (b) (4)	13 Jan 2021 19:17:35
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	10 Dec 2020 16:07:55
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	10 Dec 2020 15:53:48
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'None (None)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:53:48

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'None (None)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:53:48

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'None (None)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:53:48

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'None (None)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:53:48

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Moderate (Moderate)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:53:48

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Mild (Mild)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:53:48

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Mild (Mild)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:53:48

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Moderate (Moderate)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:53:48

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'None (None)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:53:48

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'None (None)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:53:48

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Mild (Mild)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:53:48

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Mild (Mild)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:53:48

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'None (None)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:53:48

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'None (None)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:53:48

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'None (None)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:53:48

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Mild (Mild)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:53:48

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Day 2 (Day 2)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:55:07

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered '08 Dec 2020'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:55:07

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	10 Dec 2020 15:55:07

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered empty.	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:55:07

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User entered empty.	System	10 Dec 2020 15:55:07

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered empty.	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:55:07

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'None (None)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:55:07

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'None (None)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:55:07

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'None (None)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:55:07

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'None (None)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:55:07

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Moderate (Moderate)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:55:07

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Mild (Mild)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:55:07

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Mild (Mild)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:55:07

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Moderate (Moderate)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:55:07

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'None (None)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:55:07

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'None (None)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:55:07

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Mild (Mild)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:55:07

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Mild (Mild)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:55:07

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'None (None)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:55:07

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'None (None)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:55:07

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'None (None)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:55:07

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Mild (Mild)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:55:07

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Day 3 (Day 3)'	(b) (4) Erika Faust (b) (4) (b) (4)	10 Dec 2020 15:56:28

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered '09 Dec 2020'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:56:28

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	10 Dec 2020 15:56:28

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered '97'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:56:28

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User entered '%'	System	10 Dec 2020 15:56:28

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered '98.4' F	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:56:28

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'None (None)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:56:28

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Mild (Mild)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:56:28

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'None (None)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:56:28

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'None (None)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:56:28

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Moderate (Moderate)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:56:28

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Mild (Mild)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:56:28

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Mild (Mild)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:56:28

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Moderate (Moderate)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:56:28

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'None (None)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:56:28

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'None (None)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:56:28

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Mild (Mild)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:56:28

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Mild (Mild)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:56:28

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Mild (Mild)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:56:28

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'None (None)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:56:28

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Mild (Mild)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:56:28

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:17
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Mild (Mild)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:56:28

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:08

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:26
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered '09 Dec 2020'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 16:01:54

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:08

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:26
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 16:01:54

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:08

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:26
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'No (N)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 16:01:54

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:08

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:26
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered '09 Dec 2020'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 16:01:54

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:08

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:26
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 16:01:54

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:08

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:26
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered empty.	(b) (4) Erika Faust (b) (4)	10 Dec 2020 16:01:54

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:08

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:26
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:17:01
Signature has been broken.	(b) (4)	
	Hannah Yellin (b) (4)	29 Jan 2021 17:21:33
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Hannah Yellin (b) (4)	29 Jan 2021 17:21:33
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	10 Dec 2020 16:07:55
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	10 Dec 2020 16:01:54
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:08

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:26
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:17:01
Signature has been broken.	(b) (4)	
	Hannah Yellin (b) (4)	29 Jan 2021 17:21:33
	(b) (4)	
User entered empty; reason for change Data Entry Error	Hannah Yellin (b) (4)	29 Jan 2021 17:21:33
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
	(b) (4)	
User entered 'George Washington University Hospital Lab'	Erika Faust (b) (4)	10 Dec 2020 16:01:54
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:08

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:26
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:17:01
Signature has been broken.	(b) (4)	
	Hannah Yellin (b) (4)	29 Jan 2021 17:21:33
	(b) (4)	
User entered empty; reason for change Data Entry Error	Hannah Yellin (b) (4)	29 Jan 2021 17:21:33
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	10 Dec 2020 16:01:54
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:08

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:26
User entered '0'	System	10 Dec 2020 16:01:54

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:12:08

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:05:33
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'No (N)'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:56:33

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:12:08

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:10:59
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:17:01
User entered '08 Dec 2020'	(b) (4) Hannah Yellin (b) (4)	29 Jan 2021 17:19:40
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:12:08

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:10:59
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:17:01
User entered '08:45'	(b) (4) Hannah Yellin (b) (4)	29 Jan 2021 17:19:40
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:12:08

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:10:59
User entered '08 Dec 2020 08:45'	System	29 Jan 2021 17:19:40

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:12:08

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:10:59
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:17:01
User entered 'Safety Call (Safety Call)'	(b) (4) Hannah Yellin (b) (4)	29 Jan 2021 17:19:40
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:12:08

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:10:59
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:17:01
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4)	29 Jan 2021 17:19:40
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:08

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:11:05
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:17:01
User entered '09 Dec 2020'	(b) (4) Hannah Yellin (b) (4)	29 Jan 2021 17:20:21
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:08

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:11:05
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:17:01
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	29 Jan 2021 17:20:21

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:08

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:11:05
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:17:01
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	29 Jan 2021 17:20:21
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:08

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:11:05
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:17:01
User entered '09 Dec 2020'	(b) (4) Hannah Yellin (b) (4)	29 Jan 2021 17:20:21
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:08

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:11:05
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:17:01
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Hannah Yellin (b) (4)	29 Jan 2021 17:20:21

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:08

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:11:05
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:17:01
User entered empty.	(b) (4) Hannah Yellin (b) (4)	29 Jan 2021 17:20:21
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:08

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:11:05
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:17:01
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	29 Jan 2021 17:20:21

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:08

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:11:05
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:17:01
User entered 'George Washington University Hospital Lab'	(b) (4) Hannah Yellin (b) (4)	29 Jan 2021 17:20:21

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:08

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:11:05
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:17:01
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	29 Jan 2021 17:20:21

US3542030

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:08

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:11:05
User entered '0'	System	29 Jan 2021 17:20:21

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:12:08

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:45
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '08 Mar 2021'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:04:10
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:12:08

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:45
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '09:45'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:04:10

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:12:08

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:45
User entered '08 Mar 2021 09:45'	System	10 Mar 2021 18:04:10

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:12:08

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:45
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Safety Call (Safety Call)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:04:10

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:12:08

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:45
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	10 Mar 2021 18:04:10

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Day 1 (Day 1)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:05

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '03 Mar 2021'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:05
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '0'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:05
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered missing code ND - Not Done.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:05

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User entered '%'	System	10 Mar 2021 18:06:05

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered missing code ND - Not Done.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:05
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:05
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:05
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:05
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:05
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:05
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:05
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:05
	(b) (4)	

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:05
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:05
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:05
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Mild (Mild)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:05
	(b) (4)	

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:05
	(b) (4)	

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:05
	(b) (4)	

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:05
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:05
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:12:08

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:05
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Day 2 (Day 2)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:48

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '04 Mar 2021'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:48
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '0'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:48
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered missing code ND - Not Done.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:48

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User entered '%'	System	10 Mar 2021 18:06:48

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered missing code ND - Not Done.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:48
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:48
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:48
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:48
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:48
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:48
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:48
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:48
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:48
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:48
	(b) (4)	

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:48
	(b) (4)	

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Mild (Mild)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:48
	(b) (4)	

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:48
	(b) (4)	

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:48
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:48
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:48
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:12:08

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:06:48
	(b) (4)	

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Day 3 (Day 3)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:07:25
	(b) (4)	

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '05 Mar 2021'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:07:25
	(b) (4)	

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (3)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '0'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:07:25
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered missing code ND - Not Done.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:07:25

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User entered '%'	System	10 Mar 2021 18:07:25

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered missing code ND - Not Done.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:07:25
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:07:25
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:07:25
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:07:25
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:07:25
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Mild (Mild)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:07:25
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:07:25
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:07:25
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:07:25
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:07:25
	(b) (4)	

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Form: Symptom Log (3)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:07:25
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Mild (Mild)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:07:25
	(b) (4)	

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Form: Symptom Log (3)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:07:25
	(b) (4)	

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:07:25
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:07:25
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:07:25
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:12:08

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Moderate (Moderate)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:07:25
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:08

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Day 4 (Day 4)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:05

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:08

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '06 Mar 2021'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:05
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:08

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '0'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:05
	(b) (4)	

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:08

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered missing code ND - Not Done.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:05

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:08

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User entered '%'	System	10 Mar 2021 18:08:05

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:08

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered missing code ND - Not Done.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:05
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:08

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:05
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:08

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:05
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:08

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:05
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:08

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:05
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:08

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Mild (Mild)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:05
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:08

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:05
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:08

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:05
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:08

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:05
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:08

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:05
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:08

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:05
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:08

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Mild (Mild)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:05
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:08

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:05
	(b) (4)	

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:08

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:05
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:08

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:05
	(b) (4)	

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:08

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:05
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:12:08

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Moderate (Moderate)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:05
	(b) (4)	

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:08

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Day 5 (Day 5)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:40

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:08

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '07 Mar 2021'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:40
	(b) (4)	

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:08

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '0'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:40
	(b) (4)	

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:08

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered missing code ND - Not Done.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:40
	(b) (4)	

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:08

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User entered '%'	System	10 Mar 2021 18:08:40

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:08

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered missing code ND - Not Done.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:40
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:08

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:40
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:08

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:40
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:08

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:40
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:08

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:40
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:08

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Mild (Mild)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:40
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:08

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:40
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:08

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:40
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:08

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:40
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:08

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:40
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:08

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:40
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:08

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Mild (Mild)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:40
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:08

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:40
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:08

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:40
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:08

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:40
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:08

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:40
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:12:08

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Moderate (Moderate)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:08:40
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:08

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Day 6 (Day 6)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:09:28

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:08

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '08 Mar 2021'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:09:28
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:08

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '0'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:09:28
	(b) (4)	

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:08

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered missing code ND - Not Done.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:09:28
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:08

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User entered '%'	System	10 Mar 2021 18:09:28

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:08

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered missing code ND - Not Done.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:09:28
	(b) (4)	

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:08

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:09:28
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:08

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:09:28
	(b) (4)	

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:08

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:09:28
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:08

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:09:28
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:08

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Mild (Mild)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:09:28
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:08

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:09:28
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:08

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:09:28
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:08

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:09:28
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:08

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:09:28
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:08

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:09:28
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:08

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Mild (Mild)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:09:28
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:08

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:09:28
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:08

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:09:28
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:08

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:09:28
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:08

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:09:28
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:12:08

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Moderate (Moderate)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:09:28
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:12:08

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Day 7 (Day 7)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:10:06
	(b) (4)	

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:12:08

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '09 Mar 2021'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:10:06
	(b) (4)	

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:12:08

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '0'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:10:06
	(b) (4)	

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:12:08

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered missing code ND - Not Done.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:10:06
	(b) (4)	

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:12:08

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User entered '%'	System	10 Mar 2021 18:10:06

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:12:08

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered missing code ND - Not Done.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:10:06
	(b) (4)	

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:12:08

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:10:06
	(b) (4)	

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:12:08

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:10:06
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:12:08

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:10:06
	(b) (4)	

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:12:08

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:10:06
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:12:08

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Mild (Mild)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:10:06
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:12:08

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:10:06
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:12:08

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:10:06
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:12:08

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Mild (Mild)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:10:06
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:12:08

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:10:06
	(b) (4)	

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:12:08

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:10:06
	(b) (4)	

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:12:08

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Mild (Mild)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:10:06
	(b) (4)	

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:12:08

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:10:06
	(b) (4)	

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:12:08

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:10:06
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:12:08

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:10:06
	(b) (4)	

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:12:08

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:10:06
	(b) (4)	

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:12:08

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Moderate (Moderate)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:10:06
	(b) (4)	

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:12:08

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:20:56

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Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:12:08

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:20:56

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:12:08

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 20:20:56

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:12:08

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered '97'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:20:56

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:12:08

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User entered '%'	System	11 Mar 2021 20:20:56

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:12:08

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered '98.5' F	(b) (4), (b) (6)	11 Mar 2021 20:20:56

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:12:08

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:20:56

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:12:08

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:20:56

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:12:08

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:20:56

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:12:08

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:20:56

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Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:12:08

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:20:56

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:12:08

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:20:56

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:12:08

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:20:56

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:12:08

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered 'None (None)'	(b) (4), (b) (6)	11 Mar 2021 20:20:56

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:12:08

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:20:56

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:12:08

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:20:56

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:12:08

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:20:56

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:12:08

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:20:56

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:12:08

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:20:56

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:12:08

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered 'None (None)'	(b) (4), (b) (6)	11 Mar 2021 20:20:56

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:12:08

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:20:56

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:12:08

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:51
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:20:56

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:08

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:58
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 22:22:30
User entered '10 Mar 2021'	(b) (4) David Diemert (b) (4) (b) (4)	10 Mar 2021 22:03:30

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:08

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:58
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 22:22:30
User entered 'Yes (Y)'	(b) (4) David Diemert (b) (4) (b) (4)	10 Mar 2021 22:03:30

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:08

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:58
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 22:22:30
User entered 'No (N)'	(b) (4) David Diemert (b) (4) (b) (4)	10 Mar 2021 22:03:30

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:08

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:58
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 04AUG2020 is recorded under Unscheduled visit in PPD Central lab, however the same collection date is recorded in Covid-19 Assessments and corresponding visit details not updated in EDC. Please reconcile the data and amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 05:10:49
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 04AUG2020 is recorded under Unscheduled visit in PPD Central lab, however the same collection date is recorded in Covid-19 Assessments and corresponding visit details not updated in EDC. Please reconcile the data and amend EDC or Preclarus as appropriate. Thank you.' answered with 'A sample was not collected on 04Aug2020. Per site processing lab: The aliquot tubes for the Visit 1 samples were accidentally entered by a different site, which made them unavailable to accession correctly here. The specimens had to be sent to PPD without being entered in Preclarus. This is likely an error made by GCL when reconciling them in the system.' (Site from DM).	Hannah Yellin (b) (4) (b) (4)	06 Apr 2021 17:30:39
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 04AUG2020 is recorded under Unscheduled visit in PPD Central lab, however the same collection date is recorded in Covid-19 Assessments and corresponding visit details not updated in EDC. Please reconcile the data and amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 05:35:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	10 Mar 2021 22:22:30
User entered '10 Mar 2021'	David Diemert (b) (4) (b) (4)	10 Mar 2021 22:03:30

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:08

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:58
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 22:22:30
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) David Diemert (b) (4)	10 Mar 2021 22:03:30

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:08

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:58
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 22:22:30
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	10 Mar 2021 22:03:30

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:08

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:58
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 22:22:30
User entered 'Yes (Y)'	(b) (4) David Diemert (b) (4) (b) (4)	10 Mar 2021 22:03:30

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:08

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:58
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 22:22:30
User entered 'CLIA-certified lab of Dr. Jeanne Jordan, GWU School of Public Health'	(b) (4) David Diemert (b) (4) (b) (4)	10 Mar 2021 22:03:30

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:08

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:58
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 22:22:30
User entered 'Yes (Y)'	(b) (4) David Diemert (b) (4) (b) (4)	10 Mar 2021 22:03:30

US3542030

Folder: Covid-19 Assessment 08 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:12:08

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:03:58
User entered '0'	System	10 Mar 2021 22:03:30

US3542030

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:12:08

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Erika Faust (b) (4)	10 Dec 2020 15:57:00
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:12:08

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Erika Faust (b) (4) (b) (4)	10 Dec 2020 15:57:00

US3542030

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:12:08

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	10 Dec 2020 15:57:00

US3542030

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:12:08

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Erika Faust (b) (4)	10 Dec 2020 15:57:00
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:12:08

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Erika Faust (b) (4) (b) (4)	10 Dec 2020 15:57:00

US3542030

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:12:08

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	10 Dec 2020 15:57:00

US3542030

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:12:08

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Erika Faust (b) (4)	10 Dec 2020 15:57:00
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:12:08

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Erika Faust (b) (4) (b) (4)	10 Dec 2020 15:57:00

US3542030

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:12:08

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	10 Dec 2020 15:57:00

US3542030

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:12:08

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Erika Faust (b) (4)	10 Dec 2020 15:57:00
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:12:08

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Erika Faust (b) (4) (b) (4)	10 Dec 2020 15:57:00

US3542030

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:12:08

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	10 Dec 2020 15:57:00

US3542030

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:12:08

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Erika Faust (b) (4)	10 Dec 2020 15:57:00
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:12:08

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Erika Faust (b) (4) (b) (4)	10 Dec 2020 15:57:00

US3542030

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:12:08

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	10 Dec 2020 15:57:00

US3542030

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:12:08

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Erika Faust (b) (4)	10 Dec 2020 15:57:00
	(b) (4)	

US3542030

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:12:08

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Erika Faust (b) (4) (b) (4)	10 Dec 2020 15:57:00

US3542030

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:12:08

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	10 Dec 2020 15:57:00

US3542030

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:12:08

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Erika Faust (b) (4)	10 Dec 2020 15:57:00
	(b) (4)	

US3542030

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:12:08

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Erika Faust (b) (4) (b) (4)	10 Dec 2020 15:57:00

US3542030

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:12:08

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	10 Dec 2020 15:57:00

US3542030

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	10 Dec 2020 15:57:13

US3542030

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered '09 Dec 2020'	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:57:13

US3542030

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Clinic (Clinic)'	(b) (4) Erika Faust (b) (4) (b) (4)	10 Dec 2020 15:57:13

US3542030

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User entered 'SICKD1'	System	10 Dec 2020 15:57:13

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	10 Dec 2020 15:58:25

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered '09 Dec 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	10 Dec 2020 15:58:25

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered '15:00'	(b) (4) Erika Faust (b) (4) (b) (4)	10 Dec 2020 15:58:25

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User entered '09 Dec 2020 15:00'	System	10 Dec 2020 15:58:25

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:58:25
DataPoint set to visible.	(b) (4) System	10 Dec 2020 15:57:13

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:58:25
DataPoint set to visible.	(b) (4) System	10 Dec 2020 15:57:13

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered '98.4' F	(b) (4) Erika Faust (b) (4)	10 Dec 2020 15:58:25

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Oral (Oral)'	(b) (4) Erika Faust (b) (4) (b) (4)	10 Dec 2020 15:58:25

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	10 Dec 2020 15:58:25

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered '78'	(b) (4) Erika Faust (b) (4) (b) (4)	10 Dec 2020 15:58:25

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User entered 'bpm'	System	10 Dec 2020 15:58:25

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered '16'	(b) (4) Erika Faust (b) (4) (b) (4)	10 Dec 2020 15:58:25

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User entered 'breaths/min'	System	10 Dec 2020 15:58:25

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered '133'	(b) (4) Erika Faust (b) (4) (b) (4)	10 Dec 2020 15:58:25

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User entered 'mmHg'	System	10 Dec 2020 15:58:25

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered '83'	(b) (4) Erika Faust (b) (4) (b) (4)	10 Dec 2020 15:58:25

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User entered 'mmHg'	System	10 Dec 2020 15:58:25

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04

US3542030

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	10 Dec 2020 15:58:37

US3542030

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:08

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered '09 Dec 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	10 Dec 2020 15:58:37

US3542030

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 08:12:08

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	10 Dec 2020 15:58:48

US3542030

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 08:12:08

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:55
User entered '09 Dec 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	10 Dec 2020 15:58:48

US3542030

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	10 Mar 2021 18:10:58

US3542030

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '10 Mar 2021'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:10:58
	(b) (4)	

US3542030

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Clinic (Clinic)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	10 Mar 2021 18:10:58

US3542030

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User entered 'SICKD1'	System	10 Mar 2021 18:10:58

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:17:59

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered '10 Mar 2021'	(b) (4), (b) (6)	11 Mar 2021 20:17:59

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered '08:35'	(b) (4), (b) (6)	11 Mar 2021 20:17:59

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User entered '10 Mar 2021 08:35'	System	11 Mar 2021 20:17:59

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:17:59
DataPoint set to visible.	System	10 Mar 2021 18:10:58

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:17:59
DataPoint set to visible.	System	10 Mar 2021 18:10:58

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered '98.5' F	(b) (4), (b) (6)	11 Mar 2021 20:17:59

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Mar 2021 20:17:59

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:17:59

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered '82'	(b) (4), (b) (6)	11 Mar 2021 20:17:59

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User entered 'bpm'	System	11 Mar 2021 20:17:59

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered '18'	(b) (4), (b) (6)	11 Mar 2021 20:17:59

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User entered 'breaths/min'	System	11 Mar 2021 20:17:59

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered '131'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:17:59

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User entered 'mmHg'	System	11 Mar 2021 20:17:59

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered '79'	(b) (4), (b) (6)	11 Mar 2021 20:17:59

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User entered 'mmHg'	System	11 Mar 2021 20:17:59

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04

US3542030

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04

US3542030

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:18:30

US3542030

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:08

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:18:30

US3542030

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 08:12:08

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Mar 2021 20:18:46

US3542030

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 08:12:08

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:04
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered '10 Mar 2021'	(b) (4), (b) (6)	11 Mar 2021 20:18:46

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	12 Jan 2021 17:54:41

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered '11 Jan 2021'	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:54:41
	(b) (4)	

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered 'Clinic (Clinic)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	12 Jan 2021 17:54:41

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'UNBLND_DECIDE'	System	12 Jan 2021 17:54:41

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:12:08

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered '11 Jan 2021'	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:55:02
	(b) (4)	

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:12:08

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:59:31

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:12:08

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:55:02

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:12:08

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:41
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:59:31

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:12:08

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered '11 Jan 2021'	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:55:02
	(b) (4)	

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:12:08

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered 'Placebo (Placebo)'	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:55:02

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:12:08

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 07:51:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered 'Placebo (Placebo)'	(b) (4)	
	Hannah Yellin (b) (4)	12 Jan 2021 17:55:02
	(b) (4)	

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:12:08

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 07:51:29
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered 'Placebo (Placebo)'	(b) (4)	
	Hannah Yellin (b) (4)	12 Jan 2021 17:55:02
	(b) (4)	

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:12:08

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:55:02

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:12:08

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'I'	System	12 Jan 2021 17:55:02

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:12:08

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'I'	System	12 Jan 2021 17:55:02

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:08

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered missing code ND - Not Done.	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:55:42
	(b) (4)	

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered missing code ND - Not Done.	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:55:42
	(b) (4)	

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:08

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered empty.	System	12 Jan 2021 17:55:42
DataPoint set to visible.	System	12 Jan 2021 17:55:02

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:08

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered missing code ND - Not Done.	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:55:42
	(b) (4)	

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered missing code ND - Not Done.	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:55:42
	(b) (4)	

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:08

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered empty.	System	12 Jan 2021 17:55:42
DataPoint set to visible.	System	12 Jan 2021 17:55:02

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User accepted default value 'Pre-Dose (PREDOSE)'	Hannah Yellin (b) (4) (b) (4)	12 Jan 2021 17:55:42

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:55:42

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered '11 Jan 2021'	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:55:42
	(b) (4)	

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered '13:46'	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:55:42

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered '11 Jan 2021 13:46'	System	12 Jan 2021 17:55:42

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered '97.5' F	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:55:42

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered 'Oral (Oral)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	12 Jan 2021 17:55:42

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered empty.	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:55:42
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered '105'	(b) (4) Hannah Yellin (b) (4) (b) (4)	12 Jan 2021 17:55:42

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'bpm'	System	12 Jan 2021 17:55:42

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered '16'	(b) (4) Hannah Yellin (b) (4) (b) (4)	12 Jan 2021 17:55:42

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'breaths/min'	System	12 Jan 2021 17:55:42

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered '146'	(b) (4) Hannah Yellin (b) (4) (b) (4)	12 Jan 2021 17:55:42

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'mmHg'	System	12 Jan 2021 17:55:42

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered '95'	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:55:42

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'mmHg'	System	12 Jan 2021 17:55:42

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:08

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered missing code ND - Not Done.	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:55:42
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered missing code ND - Not Done.	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:55:42
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:08

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered empty.	System	12 Jan 2021 17:55:42
DataPoint set to visible.	System	12 Jan 2021 17:55:02

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User accepted default value 'Post-Dose (POSTDOSE)'	Hannah Yellin (b) (4) (b) (4)	12 Jan 2021 17:56:20

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:56:20

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered '11 Jan 2021'	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:56:20
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered '14:26'	(b) (4) Hannah Yellin (b) (4) (b) (4)	12 Jan 2021 17:56:20

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered '11 Jan 2021 14:26'	System	12 Jan 2021 17:56:20

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered '98.4' F	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:56:20

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered 'Oral (Oral)'	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:56:20
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered empty.	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:56:20
	(b) (4)	

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered '98'	(b) (4) Hannah Yellin (b) (4) (b) (4)	12 Jan 2021 17:56:20

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'bpm'	System	12 Jan 2021 17:56:20

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered '16'	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:56:20

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'breaths/min'	System	12 Jan 2021 17:56:20

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered '147'	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:56:20
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'mmHg'	System	12 Jan 2021 17:56:20

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered '87'	(b) (4) Hannah Yellin (b) (4) (b) (4)	12 Jan 2021 17:56:20

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'mmHg'	System	12 Jan 2021 17:56:20

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:56:33

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:08

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered '11 Jan 2021'	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:56:33
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:56:55

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered '11 Jan 2021'	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:56:55

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered 'Urine (URINE)'	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:56:55
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered 'Negative (NEGATIVE)'	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:56:55
	(b) (4)	

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:56:55
	(b) (4)	

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered empty.	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:56:55
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered empty.	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:56:55

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered empty.	System	12 Jan 2021 17:56:55

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	12 Jan 2021 17:57:13

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered empty.	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:57:13
	(b) (4)	

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered empty.	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:57:13
	(b) (4)	

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'mRNA-1273'	System	12 Jan 2021 17:57:13
DataPoint set to visible.	System	12 Jan 2021 17:55:02

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered '11 Jan 2021'	(b) (4) Hannah Yellin (b) (4) (b) (4)	12 Jan 2021 17:57:13

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered '13:56'	(b) (4) Hannah Yellin (b) (4) (b) (4)	12 Jan 2021 17:57:13

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered '11 Jan 2021 13:56'	System	12 Jan 2021 17:57:13

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered 'Left Arm (LEFT ARM)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	12 Jan 2021 17:57:13

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'ONCE'	System	12 Jan 2021 17:57:13

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'INTRAMUSCULAR'	System	12 Jan 2021 17:57:13

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:57:33

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered '11 Jan 2021'	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:57:33
	(b) (4)	

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered '13:38'	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:57:33
	(b) (4)	

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:08

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered '11 Jan 2021 13:38'	System	12 Jan 2021 17:57:33

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:12:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:57:45

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:12:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered '11 Jan 2021'	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:57:45
	(b) (4)	

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:12:08

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered '13:40'	(b) (4) Hannah Yellin (b) (4) (b) (4)	12 Jan 2021 17:57:45

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:12:08

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered '11 Jan 2021 13:40'	System	12 Jan 2021 17:57:45

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:03
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4)	12 Jan 2021 17:57:50

US3542030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:15
User entered 'I'	System	12 Jan 2021 17:57:50

US3542030

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:24:38
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:17:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Mar 2021 18:21:13

US3542030

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:24:38
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:17:25
User entered '19 Jan 2021'	(b) (4), (b) (6)	15 Mar 2021 18:21:13

US3542030

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:24:38
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:17:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	15 Mar 2021 18:21:13

US3542030

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:24:38
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 20:17:25
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 18:21:13

US3542030

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:24:38
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:39:14

US3542030

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:24:38
User entered 'l'	System	09 Feb 2021 17:39:14

US3542030

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:24:38
User entered 'I'	System	09 Feb 2021 17:39:14
DataPoint set to visible.	System	09 Feb 2021 17:39:14

US3542030

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:39:57

US3542030

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered '08 Feb 2021'	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:39:57

US3542030

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered 'Clinic (Clinic)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	09 Feb 2021 17:39:57

US3542030

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User entered 'OLD29'	System	09 Feb 2021 17:39:57

US3542030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User accepted default value 'Pre-Dose (PREDOSE)'	Taylor Ladson (b) (4) (b) (4)	09 Feb 2021 17:41:33

US3542030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:41:33

US3542030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered '08 Feb 2021'	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:41:33

US3542030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered '14:14'	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:41:33

US3542030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User entered '08 Feb 2021 14:14'	System	09 Feb 2021 17:41:33

US3542030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered '98.1' F	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:41:33

US3542030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered 'Oral (Oral)'	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:41:33

US3542030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered empty.	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:41:33

US3542030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered '91'	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:41:33

US3542030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User entered 'bpm'	System	09 Feb 2021 17:41:33

US3542030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered '16'	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:41:33

US3542030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User entered 'breaths/min'	System	09 Feb 2021 17:41:33

US3542030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered '134'	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:41:33

US3542030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User entered 'mmHg'	System	09 Feb 2021 17:41:33

US3542030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered '84'	(b) (4) Taylor Ladson (b) (4) (b) (4)	09 Feb 2021 17:41:33

US3542030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User entered 'mmHg'	System	09 Feb 2021 17:41:33

US3542030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User accepted default value 'Post-Dose (POSTDOSE)'	Taylor Ladson (b) (4) (b) (4)	09 Feb 2021 17:43:18

US3542030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:43:18

US3542030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered '08 Feb 2021'	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:43:18

US3542030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered '15:28'	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:43:18

US3542030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User entered '08 Feb 2021 15:28'	System	09 Feb 2021 17:43:18

US3542030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered '98' F	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:43:18

US3542030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered 'Oral (Oral)'	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:43:18

US3542030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered empty.	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:43:18

US3542030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered '90'	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:43:18

US3542030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User entered 'bpm'	System	09 Feb 2021 17:43:18

US3542030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered '16'	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:43:18

US3542030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User entered 'breaths/min'	System	09 Feb 2021 17:43:18

US3542030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered '133'	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:43:18

US3542030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User entered 'mmHg'	System	09 Feb 2021 17:43:18

US3542030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered '81'	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:43:18

US3542030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User entered 'mmHg'	System	09 Feb 2021 17:43:18

US3542030

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:42:24

US3542030

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:08

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered '08 Feb 2021'	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:42:24

US3542030

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:42:10

US3542030

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered '08 Feb 2021'	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:42:10

US3542030

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered 'Urine (URINE)'	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:42:10

US3542030

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered 'Negative (NEGATIVE)'	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:42:10

US3542030

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:42:10

US3542030

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered empty.	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:42:10

US3542030

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered empty.	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:42:10

US3542030

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:12:08

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User entered empty.	System	09 Feb 2021 17:42:10

US3542030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:42:55

US3542030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered empty.	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:42:55

US3542030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

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)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered empty.	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:42:55

US3542030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User entered 'mRNA-1273'	System	09 Feb 2021 17:42:55
DataPoint set to visible.	System	09 Feb 2021 17:39:14

US3542030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered '08 Feb 2021'	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:42:55

US3542030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered '14:57'	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:42:55

US3542030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User entered '08 Feb 2021 14:57'	System	09 Feb 2021 17:42:55

US3542030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered 'Left Arm (LEFT ARM)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	09 Feb 2021 17:42:55

US3542030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User entered 'ONCE'	System	09 Feb 2021 17:42:55

US3542030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User entered 'INTRAMUSCULAR'	System	09 Feb 2021 17:42:55

US3542030

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:56
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	09 Feb 2021 17:42:34

US3542030

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:31:14
User entered 'I'	System	09 Feb 2021 17:42:34

US3542030

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:02
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:24:30
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	17 Feb 2021 17:38:05

US3542030

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:02
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:24:30
User entered '16 Feb 2021'	(b) (4) Erika Faust (b) (4)	17 Feb 2021 17:38:05

US3542030

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:02
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:24:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4)	17 Feb 2021 17:38:05

US3542030

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:02
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:24:30
User entered empty.	(b) (4) Erika Faust (b) (4)	17 Feb 2021 17:38:05

US3542030

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:02
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:24:30
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	17 Feb 2021 17:38:10

US3542030

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:02
User entered 'l'	System	17 Feb 2021 17:38:10

US3542030

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:29
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:08:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Mar 2021 18:08:59

US3542030

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:29
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:08:31
User entered '05 Mar 2021'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:08:59

US3542030

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:29
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:08:31
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:08:59

US3542030

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:29
User entered 'OLD57'	System	08 Mar 2021 18:08:59

US3542030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:29
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:08:31
User entered 'No (N)'	(b) (4), (b) (6)	08 Mar 2021 18:09:08

US3542030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:29
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:08:31
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 18:09:08

US3542030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:29
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:08:31
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:09:08

US3542030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:29
User entered empty.	System	08 Mar 2021 18:09:08

US3542030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:29
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:08:31
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 18:09:08

US3542030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:29
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:08:31
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 18:09:08

US3542030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:29
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:08:31
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:09:08

US3542030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:29
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:08:31
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:09:08

US3542030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:29
User entered empty.	System	08 Mar 2021 18:09:08

US3542030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:29
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:08:31
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 18:09:08

US3542030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:29
User entered empty.	System	08 Mar 2021 18:09:08

US3542030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:29
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:08:31
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:09:08

US3542030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:29
User entered empty.	System	08 Mar 2021 18:09:08

US3542030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:29
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:08:31
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 18:09:08

US3542030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:29
User entered empty.	System	08 Mar 2021 18:09:08

US3542030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:29

US3542030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:08

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:29

US3542030

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:29
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:08:31
User entered 'No (N)'	(b) (4), (b) (6)	08 Mar 2021 18:09:15

US3542030

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:08

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:29
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:08:31
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:09:15

US3542030

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:29
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:08:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Mar 2021 18:09:28

US3542030

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:29
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:08:31
User entered '05 Mar 2021'	(b) (4), (b) (6)	08 Mar 2021 18:09:28

US3542030

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:08

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:29
User signature succeeded.	David Diemert (b) (4)	09 Mar 2021 04:08:31
User entered '13:46'	(b) (4), (b) (6)	08 Mar 2021 18:09:28

US3542030

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:08

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:29
User entered '05 Mar 2021 13:46'	System	08 Mar 2021 18:09:28

US3542030

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:12:08

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:47:54
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	08 Sep 2020 17:39:44

US3542030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03

US3542030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03
User closed query 'Per DM CLR: Please specify the location of INSECT BITES (e.g., GENERALIZED, BOTH ARMS, LEFT LEG, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 09:44:00
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Arthropod bite, LLT: Insect bite NOS - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 11:11:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 11:11:19
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
Data point term sent to Coder	System	07 Oct 2020 22:10:19
Query 'Per DM CLR: Please specify the location of INSECT BITES (e.g., GENERALIZED, BOTH ARMS, LEFT LEG, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'Location added.' (Site from DM).	David Diemert (b) (4)	07 Oct 2020 22:09:59
Coding entries removed.	David Diemert (b) (4)	07 Oct 2020 22:09:46
Signature has been broken.	David Diemert (b) (4)	07 Oct 2020 22:09:46
User entered 'INSECT BITES, both legs' reason for change: New Information	David Diemert (b) (4)	07 Oct 2020 22:09:46
User opened query 'Per DM CLR: Please specify the location of INSECT BITES (e.g., GENERALIZED, BOTH ARMS, LEFT LEG, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 05:01:18
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Arthropod bite, LLT: Insect bite NOS - version MedDRA\23.0.	Coder Import (b) (4)	10 Sep 2020 10:20:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. User signature succeeded.	Coder Import (b) (4) (b) (4) David Diemert (b) (4) (b) (4)	10 Sep 2020 10:20:42 09 Sep 2020 01:41:06
Data point term sent to Coder	System	08 Sep 2020 17:48:19
User entered 'Insect Bites'	Madhu Balachandran (b) (4)	08 Sep 2020 17:47:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	08 Sep 2020 17:47:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	08 Sep 2020 17:47:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	08 Sep 2020 17:47:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered '27 Aug 2020'	(b) (4) Madhu Balachandran (b) (4)	08 Sep 2020 17:47:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	08 Sep 2020 17:47:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03
User entered empty.	System	08 Sep 2020 17:47:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	21 Oct 2020 18:36:18
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Erika Faust (b) (4)	21 Oct 2020 18:36:18
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered 'Yes (Y)'	(b) (4)	
	Madhu Balachandran	08 Sep 2020 17:47:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	21 Oct 2020 18:36:18
User entered '29 Aug 2020' reason for change: New Information	(b) (4)	
	Erika Faust (b) (4)	21 Oct 2020 18:36:18
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
	(b) (4)	
User entered empty.	Madhu Balachandran	08 Sep 2020 17:47:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	08 Sep 2020 17:47:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03
User entered empty.	System	08 Sep 2020 17:47:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
Signature has been broken.	(b) (4)	
	Hannah Yellin (b) (4)	18 Sep 2020 18:18:38
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Hannah Yellin (b) (4)	18 Sep 2020 18:18:38
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Madhu Balachandran	08 Sep 2020 17:47:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	08 Sep 2020 17:47:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	08 Sep 2020 17:47:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	08 Sep 2020 17:47:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	08 Sep 2020 17:47:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	08 Sep 2020 17:47:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	08 Sep 2020 17:47:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	08 Sep 2020 17:47:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	08 Sep 2020 17:47:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	08 Sep 2020 17:47:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	08 Sep 2020 17:47:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	08 Sep 2020 17:47:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered 'Not Related (NOT RELATED)'	(b) (4) Madhu Balachandran (b) (4)	08 Sep 2020 17:47:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered 'Not Related (NOT RELATED)'	(b) (4) Madhu Balachandran (b) (4)	08 Sep 2020 17:47:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered 'None (NONE)'	(b) (4) Madhu Balachandran (b) (4)	08 Sep 2020 17:47:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:50
Signature has been broken.	(b) (4)	
	Elissa Malkin (b) (4)	17 Dec 2020 17:59:27
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	20 Nov 2020 04:10:06
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	18 Nov 2020 21:50:14
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	23 Oct 2020 13:45:37
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field. (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 04:29:06
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'Field was updated to con med taken.' (Site from DM).	Erika Faust (b) (4)	21 Oct 2020 18:36:46
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	21 Oct 2020 18:36:18
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Erika Faust (b) (4)	21 Oct 2020 18:36:18
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field. (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 09:06:35
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered '1'	(b) (4)	
	Madhu Balachandran (b) (4)	08 Sep 2020 17:47:33

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Folder: Adverse Events

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Generated On: 10 Jun 2021 08:12:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:50
Signature has been broken.	(b) (4)	
	Elissa Malkin (b) (4)	17 Dec 2020 18:01:10
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
	(b) (4)	
Signature has been broken.	Erika Faust (b) (4)	21 Oct 2020 18:36:18
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Erika Faust (b) (4)	21 Oct 2020 18:36:18
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
	(b) (4)	
User entered '0'	Madhu Balachandran	08 Sep 2020 17:47:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	08 Sep 2020 17:47:33

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	21 Oct 2020 18:36:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
New Information	Erika Faust (b) (4)	21 Oct 2020 18:36:18
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4)	
	Madhu Balachandran	08 Sep 2020 17:47:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	08 Sep 2020 17:47:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	08 Sep 2020 17:47:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03
User entered '0'	System	08 Sep 2020 17:47:33

US3542030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03
User entered '0'	System	08 Sep 2020 17:47:33

US3542030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:08

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:08

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:08

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Gastroenteritis, LLT: Gastroenteritis - version MedDRA\23.0.	Coder Import (b) (4)	14 Sep 2020 17:10:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Sep 2020 17:10:44
Data point term sent to Coder	System	14 Sep 2020 17:09:40
User entered 'Gastroenteritis'	Madhu Balachandran (b) (4)	14 Sep 2020 17:09:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:09:01

US3542030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:09:01

US3542030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:09:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:08

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered '04 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Madhu Balachandran	15 Sep 2020 20:02:02
User entered '3 Sep 2020'	(b) (4)	
	Madhu Balachandran	14 Sep 2020 17:09:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:08

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:09:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05
User entered empty.	System	14 Sep 2020 17:09:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:09:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered '6 Sep 2020'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:09:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:08

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:09:01

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Folder: Adverse Events

Form: Adverse Events (2)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05
User entered empty.	System	14 Sep 2020 17:09:01

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Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
reason for change: New Information	Madhu Balachandran	15 Sep 2020 20:01:42
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4)	
	Madhu Balachandran	14 Sep 2020 17:09:01
	(b) (4)	

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Folder: Adverse Events

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:09:01

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Folder: Adverse Events

Form: Adverse Events (2)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:09:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:08

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:09:01

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Folder: Adverse Events

Form: Adverse Events (2)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:09:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:09:01

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Folder: Adverse Events

Form: Adverse Events (2)

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:09:01

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:09:01

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:09:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:09:01

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:09:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:08

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:09:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:09:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 17:09:13
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Madhu Balachandran	14 Sep 2020 17:09:13
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	14 Sep 2020 17:09:01
	Madhu Balachandran	14 Sep 2020 17:09:01
	(b) (4)	

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered 'None (NONE)'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:09:01

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Folder: Adverse Events

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
	System	14 Sep 2020 17:09:13
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	14 Sep 2020 17:09:01
User entered '0'	Madhu Balachandran	14 Sep 2020 17:09:01
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Madhu Balachandran	14 Sep 2020 17:09:13
User entered '0'	(b) (4)	
	Madhu Balachandran	14 Sep 2020 17:09:01
	(b) (4)	

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Folder: Adverse Events

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:09:01

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:09:01

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Folder: Adverse Events

Form: Adverse Events (2)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:09:01

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:09:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:08

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05
User entered '0'	System	14 Sep 2020 17:09:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05
User entered '0'	System	14 Sep 2020 17:09:01

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:05

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Folder: Adverse Events

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23
User signature succeeded.	David Diemert (b) (4)	22 Mar 2021 19:21:56
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Cellulitis, LLT: Cellulitis of leg - version MedDRA\23.0.	Coder Import (b) (4)	22 Mar 2021 15:29:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	22 Mar 2021 15:29:46
Data point term sent to Coder	System	22 Mar 2021 15:29:04
User closed query 'For coding purposes, please specify the location of the Cellulitis and update the term with your response.' (Site from System).	System	22 Mar 2021 15:28:25
Query 'For coding purposes, please specify the location of the Cellulitis and update the term with your response.' answered with 'Updated' (Site from System).	David Diemert (b) (4)	22 Mar 2021 15:28:25
Coding entries removed.	David Diemert (b) (4)	22 Mar 2021 15:28:17
Signature has been broken.	David Diemert (b) (4)	22 Mar 2021 15:28:17
User entered 'CELLULITIS of left leg' reason for change: Per Query Resolution	David Diemert (b) (4)	22 Mar 2021 15:28:17
User opened query 'For coding purposes, please specify the location of the Cellulitis and update the term with your response.' (Site from System).	Coder Import (b) (4)	20 Mar 2021 10:58:19
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Cellulitis, LLT: Cellulitis - version MedDRA\23.0.	Coder Import (b) (4)	22 Sep 2020 14:56:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	22 Sep 2020 14:56:40
Data point term sent to Coder	System	22 Sep 2020 14:56:19
User entered 'Cellulitis'	Hannah Yellin (b) (4)	22 Sep 2020 14:56:09

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Folder: Adverse Events

Form: Adverse Events (3)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 14:56:09

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Folder: Adverse Events

Form: Adverse Events (3)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 14:56:09

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 14:56:09

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Folder: Adverse Events

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered '29 Aug 2020'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 14:56:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered empty.	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 14:56:09

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Folder: Adverse Events

Form: Adverse Events (3)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23
User entered empty.	System	22 Sep 2020 14:56:09

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Folder: Adverse Events

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 14:56:09

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Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered '07 Sep 2020'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 14:56:09

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:08

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered empty.	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 14:56:09

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Folder: Adverse Events

Form: Adverse Events (3)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23
User entered empty.	System	22 Sep 2020 14:56:09

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:08

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 14:56:09

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 14:56:09

US3542030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:08

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 14:56:09

US3542030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:08

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered '0'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 14:56:09

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 14:56:09

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 14:56:09

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:08

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered empty.	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 14:56:09

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered empty.	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 14:56:09

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 14:56:09

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Folder: Adverse Events

Form: Adverse Events (3)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 14:56:09

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Folder: Adverse Events

Form: Adverse Events (3)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 14:56:09

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered '0'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 14:56:09

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'Not Related (NOT RELATED)'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 14:56:09

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'Not Related (NOT RELATED)'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 14:56:09

US3542030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:08

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'None (NONE)'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 14:56:09

US3542030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:08

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 14:56:09

US3542030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'l'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 14:56:09

US3542030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 14:56:09

US3542030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:08

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 14:56:09

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 14:56:09

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:08

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 14:56:09

US3542030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:08

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23
User entered '0'	System	22 Sep 2020 14:56:09

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23
User entered 'I'	System	22 Sep 2020 14:56:09

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:08

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:23

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:10:06
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Abdominal and gastrointestinal injuries NEC, PT: Tooth fracture, LLT: Tooth fracture - version MedDRA\23.0.	Coder Import (b) (4)	19 Nov 2020 06:53:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	19 Nov 2020 06:53:54
Data point term sent to Coder	System	18 Nov 2020 21:44:15
User closed query 'For coding purposes, CROWN REMOVAL is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' (Site from System).	System	18 Nov 2020 21:43:47
Query 'For coding purposes, CROWN REMOVAL is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' answered with 'Corrected.' (Site from System).	David Diemert (b) (4)	18 Nov 2020 21:43:47
Coding entries removed.	David Diemert (b) (4)	18 Nov 2020 21:43:37
Signature has been broken.	David Diemert (b) (4)	18 Nov 2020 21:43:37
User entered 'Tooth CROWN cracking' reason for change: Per Query Resolution	David Diemert (b) (4)	18 Nov 2020 21:43:37
User opened query 'For coding purposes, CROWN REMOVAL is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' (Site from System).	Coder Import (b) (4)	18 Nov 2020 14:28:05
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User closed query 'Per MM: Please split terms.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 04:31:44

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Dental and gingival therapeutic procedures, PT: Artificial crown procedure, LLT: Artificial crown removal - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 21:16:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 21:16:32
Query 'Per MM: Please split terms.' answered with 'updated' (Site from DM).	Elissa Malkin (b) (4)	20 Oct 2020 21:00:32
Data point term sent to Coder	System	20 Oct 2020 20:59:52
Coding entries removed.	Elissa Malkin (b) (4)	20 Oct 2020 20:59:35
Signature has been broken.	Elissa Malkin (b) (4)	20 Oct 2020 20:59:35
User entered 'CROWN REMOVAL' reason for change: Per Query Resolution	Elissa Malkin (b) (4)	20 Oct 2020 20:59:35
User opened query 'Per MM: Please split terms.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 16:19:07
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Abdominal and gastrointestinal injuries NEC, PT: Tooth injury, LLT: Tooth damage - version MedDRA\23.0.	Coder Import (b) (4)	03 Oct 2020 04:26:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	03 Oct 2020 04:26:48
Data point term sent to Coder	System	02 Oct 2020 20:11:55
User entered 'Tooth Damage (crown removal/replacement)'	Erika Faust (b) (4)	02 Oct 2020 20:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 20:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
User entered 'No (N)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 20:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
User entered 'No (N)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 20:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:10:06
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '01 Sep 2020' reason for change: Per Query Resolution	System	18 Nov 2020 21:49:48
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	David Diemert (b) (4)	18 Nov 2020 21:49:48
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered ' Sep 2020' (non-conformant).	System	18 Nov 2020 21:48:08
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Nov 2020 21:48:08
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Nov 2020 21:48:08
User entered ' Sep 2020' (non-conformant).	David Diemert (b) (4)	18 Nov 2020 21:48:08
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
Signature has been broken.	System	18 Nov 2020 21:43:37
User entered 'UN Sep 2020' (non-conformant).	David Diemert (b) (4)	18 Nov 2020 21:43:37
User signature succeeded.	(b) (4)	
User entered '23 Sep 2020'	David Diemert (b) (4)	18 Nov 2020 21:43:37
	(b) (4)	
	David Diemert (b) (4)	08 Oct 2020 02:52:08
	(b) (4)	
	Erika Faust (b) (4)	02 Oct 2020 20:11:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	02 Oct 2020 20:12:00
User entered empty; reason for change Per Query Resolution	Erika Faust (b) (4)	02 Oct 2020 20:12:00
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	02 Oct 2020 20:11:32
User entered '13:00'	Erika Faust (b) (4)	02 Oct 2020 20:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26
User entered empty.	System	02 Oct 2020 20:12:00
User entered '23 Sep 2020 13:00'	System	02 Oct 2020 20:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
User entered 'No (N)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 20:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
User entered '23 Sep 2020'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 20:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4) System	02 Oct 2020 20:12:00
User entered empty; reason for change Per Query Resolution	Erika Faust (b) (4)	02 Oct 2020 20:12:00
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4) System	02 Oct 2020 20:11:32
User entered '19:28'	Erika Faust (b) (4)	02 Oct 2020 20:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26
User entered empty.	System	02 Oct 2020 20:12:00
User entered '23 Sep 2020 19:28'	System	02 Oct 2020 20:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 20:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
User entered 'No (N)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 20:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 20:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 20:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 20:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
User entered empty.	(b) (4) Erika Faust (b) (4)	02 Oct 2020 20:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
User entered empty.	(b) (4) Erika Faust (b) (4)	02 Oct 2020 20:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
User entered empty.	(b) (4) Erika Faust (b) (4)	02 Oct 2020 20:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
User entered empty.	(b) (4) Erika Faust (b) (4)	02 Oct 2020 20:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 20:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 20:11:32

US3542030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 20:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 20:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 20:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
User entered 'None (NONE)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 20:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 20:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:50
Signature has been broken.	(b) (4)	
	Elissa Malkin (b) (4)	17 Dec 2020 17:54:25
	(b) (4)	
User entered '0' reason for change: Per Query Resolution	Elissa Malkin (b) (4)	17 Dec 2020 17:54:25
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
	(b) (4)	
User entered '1'	Erika Faust (b) (4)	02 Oct 2020 20:11:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26
User closed query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConProc recorded that mach this AE during this timeframe. Review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 09:12:50
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:50
Query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConProc recorded that mach this AE during this timeframe. Review and update eCRF as appropriate.' answered with 'updated' (Site from DM).	Elissa Malkin (b) (4)	17 Dec 2020 17:54:40
Signature has been broken.	Elissa Malkin (b) (4)	17 Dec 2020 17:54:25
User entered '1' reason for change: Per Query Resolution	Elissa Malkin (b) (4)	17 Dec 2020 17:54:25
User opened query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConProc recorded that mach this AE during this timeframe. Review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 06:09:17
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
User entered '0'	Erika Faust (b) (4)	02 Oct 2020 20:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 20:11:32

US3542030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
User entered empty.	(b) (4) Erika Faust (b) (4)	02 Oct 2020 20:11:32

US3542030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
User entered empty.	(b) (4) Erika Faust (b) (4)	02 Oct 2020 20:11:32

US3542030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26
User entered '0'	System	02 Oct 2020 20:11:32

US3542030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26
User entered 'I'	System	02 Oct 2020 20:11:32

US3542030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:12:08

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:26

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User coded data point as SOC: Gastrointestinal disorders, HLGT: Dental and gingival conditions, HLT: Dental pain and sensation disorders, PT: Toothache, LLT: Tooth pain - version MedDRA\\23.0.	Coder Import (b) (4)	22 Oct 2020 16:24:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Oct 2020 16:24:42
Data point term sent to Coder	System	22 Oct 2020 16:23:34
User entered 'Tooth Pain'	Erika Faust (b) (4)	22 Oct 2020 16:23:13

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:23:13

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered 'No (N)'	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:23:13

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered 'No (N)'	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:23:13

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered '19 Oct 2020'	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:23:13

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered empty.	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:23:13

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48
User entered empty.	System	22 Oct 2020 16:23:13

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered 'No (N)'	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:23:13

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered '19 Oct 2020'	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:23:13

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:23:13

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48
User entered empty.	System	22 Oct 2020 16:23:13

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:23:13

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered 'No (N)'	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:23:13

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:23:13

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:23:13

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered '0'	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:23:13

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered empty.	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:23:13

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered empty.	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:23:13

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered empty.	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:23:13

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered empty.	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:23:13

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:23:13

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:23:13

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:23:13

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered 'Not Related (NOT RELATED)'	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:23:13

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered 'Not Related (NOT RELATED)'	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:23:13

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered 'None (NONE)'	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:23:13

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered '0'	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:23:13

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered 'l'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:23:13

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:23:13

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:23:13

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered empty.	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:23:13

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:23:13

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48
User entered '0'	System	22 Oct 2020 16:23:13

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48
User entered 'I'	System	22 Oct 2020 16:23:13

US3542030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:12:08

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:48

US3542030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:12:08

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Pharyngitis, LLT: Pharyngitis - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 18:30:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 18:30:56
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Pharyngitis, LLT: Pharyngitis - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 18:16:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 18:16:00
Data point term sent to Coder	System	10 Mar 2021 18:15:04
User entered 'Pharyngitis'	Hannah Yellin (b) (4)	10 Mar 2021 18:15:02

US3542030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:12:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:15:02

US3542030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:12:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:15:02

US3542030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:12:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:15:02

US3542030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '03 Mar 2021'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:15:02

US3542030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:12:08

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered empty.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:15:02

US3542030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:12:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Mar 2021 18:15:02

US3542030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:15:02

US3542030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered empty.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:15:02

US3542030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:12:08

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered empty.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:15:02
	(b) (4)	

US3542030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:12:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Mar 2021 18:15:02

US3542030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:12:08

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:15:02

US3542030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:12:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:15:02

US3542030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:12:08

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '0'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:15:02

US3542030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:12:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '0'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:15:02

US3542030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:12:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '0'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:15:02

US3542030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:12:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered empty.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:15:02

US3542030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:12:08

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered empty.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:15:02

US3542030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:12:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered empty.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:15:02

US3542030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:12:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered empty.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:15:02

US3542030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:12:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '0'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:15:02

US3542030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:12:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '0'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:15:02

US3542030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:12:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '0'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:15:02

US3542030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:12:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Not Related (NOT RELATED)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:15:02

US3542030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:12:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Not Related (NOT RELATED)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:15:02

US3542030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:12:08

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:15:02

US3542030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:12:08

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '0'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:15:02

US3542030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:12:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'l'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:15:02

US3542030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:12:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '0'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:15:02

US3542030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:12:08

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:15:02

US3542030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:12:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered empty.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:15:02

US3542030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:12:08

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered empty.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:15:02

US3542030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:12:08

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Mar 2021 18:15:02

US3542030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:12:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Mar 2021 18:15:02

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 20:34:43
User coded data point as SOC: Gastrointestinal disorders, HLGT: Dental and gingival conditions, HLT: Dental pain and sensation disorders, PT: Toothache, LLT: Tooth pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	23 Mar 2021 20:19:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 20:19:51
Data point term sent to Coder	System	23 Mar 2021 20:19:34
User entered 'Tooth pain'	David Diemert (b) (4) (b) (4)	23 Mar 2021 20:19:16

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 20:34:43
User entered 'Yes (Y)'	(b) (4) David Diemert (b) (4) (b) (4)	23 Mar 2021 20:19:16

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 20:34:43
User entered 'No (N)'	(b) (4) David Diemert (b) (4) (b) (4)	23 Mar 2021 20:19:16

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 20:34:43
User entered 'No (N)'	(b) (4) David Diemert (b) (4) (b) (4)	23 Mar 2021 20:19:16

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 20:34:43
User entered '09 Mar 2021'	(b) (4) David Diemert (b) (4)	23 Mar 2021 20:19:16

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 20:34:43
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	23 Mar 2021 20:19:16

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43
User entered empty.	System	23 Mar 2021 20:19:16

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 20:34:43
User entered 'No (N)'	(b) (4) David Diemert (b) (4) (b) (4)	23 Mar 2021 20:19:16

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 20:34:43
User entered '09 Mar 2021'	(b) (4) David Diemert (b) (4) (b) (4)	23 Mar 2021 20:19:16

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 20:34:43
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	23 Mar 2021 20:19:16

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43
User entered empty.	System	23 Mar 2021 20:19:16

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 20:34:43
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) David Diemert (b) (4) (b) (4)	23 Mar 2021 20:19:16

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 20:34:43
User entered 'No (N)'	(b) (4) David Diemert (b) (4) (b) (4)	23 Mar 2021 20:19:16

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 20:34:43
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	23 Mar 2021 20:19:16

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 20:34:43
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	23 Mar 2021 20:19:16

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 20:34:43
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	23 Mar 2021 20:19:16

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 20:34:43
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	23 Mar 2021 20:19:16

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 20:34:43
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	23 Mar 2021 20:19:16

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 20:34:43
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	23 Mar 2021 20:19:16

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 20:34:43
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	23 Mar 2021 20:19:16

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 20:34:43
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	23 Mar 2021 20:19:16

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 20:34:43
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	23 Mar 2021 20:19:16

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 20:34:43
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	23 Mar 2021 20:19:16

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 20:34:43
User entered 'Not Related (NOT RELATED)'	(b) (4) David Diemert (b) (4) (b) (4)	23 Mar 2021 20:19:16

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 20:34:43
User entered 'Not Related (NOT RELATED)'	(b) (4) David Diemert (b) (4) (b) (4)	23 Mar 2021 20:19:16

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 20:34:43
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) David Diemert (b) (4) (b) (4)	23 Mar 2021 20:19:16

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 20:34:43
User entered '0'	(b) (4) David Diemert (b) (4) (b) (4)	23 Mar 2021 20:19:16

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 20:34:43
User entered 'l'	(b) (4) David Diemert (b) (4) (b) (4)	23 Mar 2021 20:19:16

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43
User closed query 'Per DM CLR: Please review response as there is a Concomitant Procedure (#5) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 06:05:49
Query 'Per DM CLR: Please review response as there is a Concomitant Procedure (#5) recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'The tooth pain was caused by the procedure. The procedure wasn't performed to treat the tooth pain. No changes needed.' (Site from DM).	David Diemert (b) (4) (b) (4)	05 Apr 2021 14:10:05
User opened query 'Per DM CLR: Please review response as there is a Concomitant Procedure (#5) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 09:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Mar 2021 20:34:43
User entered '0'	David Diemert (b) (4) (b) (4)	23 Mar 2021 20:19:16

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 20:34:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) David Diemert (b) (4) (b) (4)	23 Mar 2021 20:19:16

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 20:34:43
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	23 Mar 2021 20:19:16

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43
User signature succeeded.	David Diemert (b) (4)	23 Mar 2021 20:34:43
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	23 Mar 2021 20:19:16

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43
User entered '0'	System	23 Mar 2021 20:19:16

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43
User entered 'I'	System	23 Mar 2021 20:19:16

US3542030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:12:08

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:23:43

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	27 Apr 2021 18:16:06
User entered 'USA-US084-2021-mRNA-1273-P301000011'	System	27 Apr 2021 18:14:28
User entered 'New'	(b) (4), (b) (6)	27 Apr 2021 18:14:28

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Morbid obesity - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	27 Apr 2021 15:07:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Apr 2021 15:07:54
Data point term sent to Coder	System	27 Apr 2021 15:01:23
User entered 'Morbid obesity'	Caroline Thoreson (b) (4) (b) (4)	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Yes (Y)'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '22 Apr 2021'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Yes (Y)'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Yes (Y)'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'I'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '22 Apr 2021'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '23 Apr 2021'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

None

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'I'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'I'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Participant was hospitalized 22-23-APR-2021 for planned sleeve gastrectomy for morbid obesity. Participant also underwent hiatal hernia repair (incidentally found during surgery).'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:12:08

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	27 Apr 2021 15:01:06

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:17:00
User entered 'USA-US084-2021-mRNA-1273-P301000011'	(b) (4), (b) (6)	27 Apr 2021 18:16:55

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Diaphragmatic hernias, PT: Hiatus hernia, LLT: Hiatal hernia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	27 Apr 2021 15:13:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Apr 2021 15:13:37
Data point term sent to Coder	System	27 Apr 2021 15:03:34
User entered 'Hiatal hernia'	Caroline Thoreson (b) (4) (b) (4)	27 Apr 2021 15:02:30

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Yes (Y)'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:02:30

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:02:30

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:02:30

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '22 Apr 2021'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:02:30

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:02:30

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 15:02:30

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:02:30

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '23 Apr 2021'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:02:30

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:02:30

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 15:02:30

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	27 Apr 2021 15:02:30

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Yes (Y)'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:02:30

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:02:30

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:02:30

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'I'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:02:30

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '22 Apr 2021'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:02:30

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '23 Apr 2021'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:02:30

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:02:30

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:02:30

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:02:30

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:02:30

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:02:30

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:02:30

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:02:30

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:02:30

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

None

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:02:30

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:02:30

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'I'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:02:30

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:02:30

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	27 Apr 2021 15:02:30

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Participant underwent sleeve gastrectomy on 22-APR-2021 for morbid obesity. During surgery, a hiatal hernia was incidentally found and repaired. Participant was discharged on 23-APR-2021.'	(b) (4)	
	Caroline Thoreson (b) (4)	27 Apr 2021 15:02:30
	(b) (4)	

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	27 Apr 2021 15:02:30

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	27 Apr 2021 15:02:30

US3542030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:12:08

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	27 Apr 2021 15:02:30

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:12:08

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:47:54
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:01:25

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Aug 2020 20:04:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Aug 2020 20:04:40
Data point term sent to Coder Coding entries removed.	System Hannah Yellin (b) (4)	25 Aug 2020 20:03:23 25 Aug 2020 20:02:54
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS FOR SYSTEMIC USE, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 18:27:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 18:27:20
Data point term sent to Coder User entered 'Albuterol'	System Taylor Ladson (b) (4)	21 Aug 2020 18:25:52 21 Aug 2020 18:25:30

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:25:30

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Mild asthma'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:25:30

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	22 Oct 2020 16:15:03
User closed query ""	(b) (4)	
Per DM CLR: Please provide the actual dose for this medication instead of number of puffs as there are various dosage options for this drug. Update Con Med eCRF as appropriate. "	(b) (4), (b) (6)	09 Oct 2020 08:35:48
' (Site from DM).		
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
Query ""	(b) (4)	
Per DM CLR: Please provide the actual dose for this medication instead of number of puffs as there are various dosage options for this drug. Update Con Med eCRF as appropriate. "	David Diemert (b) (4)	07 Oct 2020 22:13:05
' answered with 'Dose updated.' (Site from DM).	(b) (4)	
Signature has been broken.	David Diemert (b) (4)	07 Oct 2020 22:12:58
	(b) (4)	
User entered '400' reason for change: New Information	David Diemert (b) (4)	07 Oct 2020 22:12:58
User opened query ""	(b) (4)	
Per DM CLR: Please provide the actual dose for this medication instead of number of puffs as there are various dosage options for this drug. Update Con Med eCRF as appropriate. "	(b) (4), (b) (6)	05 Oct 2020 08:30:53
' (Site from DM).		
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:17
	(b) (4)	
Signature has been broken.	Taylor Ladson (b) (4)	25 Sep 2020 18:48:02
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
	(b) (4)	
User entered '2'	Taylor Ladson (b) (4)	21 Aug 2020 18:25:30
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User		Time (GMT)
User signature succeeded.	David Diemert	(b) (4)	08 Oct 2020 02:52:08
	(b) (4)		
Signature has been broken.	David Diemert	(b) (4)	07 Oct 2020 22:12:58
	(b) (4)		
User entered 'ug (ug)' reason for change: Data Entry Error	David Diemert	(b) (4)	07 Oct 2020 22:12:58
	(b) (4)		
User signature succeeded.	David Diemert	(b) (4)	27 Aug 2020 15:36:36
	(b) (4)		
User entered 'puff (PUFF)'	Taylor Ladson	(b) (4)	21 Aug 2020 18:25:30
	(b) (4)		

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:17
Signature has been broken.	(b) (4) Taylor Ladson (b) (4)	25 Sep 2020 18:48:22
User signature succeeded.	(b) (4) David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:25:30
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'as needed (PRN)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:25:30

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:08

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
Signature has been broken.	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:20:10
User signature succeeded.	(b) (4) David Diemert (b) (4)	29 Sep 2020 04:14:17
Signature has been broken.	(b) (4) Taylor Ladson (b) (4)	25 Sep 2020 18:48:18
User signature succeeded.	(b) (4) David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:25:30
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Data Entry Error	(b) (4) Hannah Yellin (b) (4)	25 Aug 2020 20:02:54
User entered 'Oral (ORAL)'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 18:25:30

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:25:30

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'un UNK 1975'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:25:30

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:25:30

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:25:30

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:17
Signature has been broken.	(b) (4) Taylor Ladson (b) (4)	25 Sep 2020 18:48:42
User signature succeeded.	(b) (4) David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:25:30
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 18:25:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 18:25:42
User entered 'No (N)' reason for change: Per Query Resolution	Taylor Ladson (b) (4)	21 Aug 2020 18:25:42
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 18:25:30
User entered empty.	Taylor Ladson (b) (4)	21 Aug 2020 18:25:30
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 18:25:30

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 18:25:30

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 18:25:30

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Aug 2020 18:27:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 18:27:54
Data point term sent to Coder	System	21 Aug 2020 18:26:54
User entered 'Metformin'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 18:26:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:26:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Diabetes mellitus'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:26:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query "" Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. " ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 08:37:37
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
Query "" Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. " ' answered with 'Dose updated.' (Site from DM).	David Diemert (b) (4)	07 Oct 2020 22:13:55
Signature has been broken.	David Diemert (b) (4)	07 Oct 2020 22:13:49
User entered '1000' reason for change: New Information	David Diemert (b) (4)	07 Oct 2020 22:13:49
User opened query "" Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. " ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 09:47:46
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '2'	Taylor Ladson (b) (4)	21 Aug 2020 18:26:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	07 Oct 2020 22:13:49
	(b) (4)	
User entered 'mg (mg)' reason for change: New Information	David Diemert (b) (4)	07 Oct 2020 22:13:49
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
	(b) (4)	
User entered 'tablet (TABLET)'	Taylor Ladson (b) (4)	21 Aug 2020 18:26:34
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:26:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'twice daily (BID)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:26:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:08

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:26:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:26:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:26:34
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'un UNK 2005'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:26:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:26:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:26:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:26:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:26:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Aug 2020 18:26:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Aug 2020 18:26:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 18:26:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
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.	(b) (4) Coder Import (b) (4)	21 Aug 2020 18:29:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 18:29:21
Data point term sent to Coder	System	21 Aug 2020 18:27:58
User entered 'Multivitamin'	Taylor Ladson (b) (4)	21 Aug 2020 18:27:50

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:27:50

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Supplement'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:27:50

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '1' reason for change: Data Entry Error	(b) (4) Hannah Yellin (b) (4)	25 Aug 2020 20:05:19
User entered 'un'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:27:50

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'tablet (TABLET)' reason for change:	(b) (4)	
Data Entry Error	Hannah Yellin (b) (4)	25 Aug 2020 20:05:19
User entered 'Other (OTHER)'	(b) (4)	
	Taylor Ladson (b) (4)	21 Aug 2020 18:27:50
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty; reason for change Per Query Resolution	(b) (4) Hannah Yellin (b) (4)	25 Aug 2020 20:05:19
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	21 Aug 2020 18:28:03
User entered 'unknown' reason for change: Per Query Resolution	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 18:28:03
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	21 Aug 2020 18:27:50
User entered empty.	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 18:27:50

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'once daily (QD)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:27:50

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:27:50

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:27:50

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:27:50

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'un UNK 1993'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:27:50

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:27:50

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:27:50

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:27:50

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:27:50

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	21 Aug 2020 18:27:50

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Aug 2020 18:27:50

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 18:27:50

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
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.	(b) (4) Coder Import (b) (4)	21 Aug 2020 18:29:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 18:29:22
Data point term sent to Coder	System	21 Aug 2020 18:29:01
User entered 'Vitamin d'	Taylor Ladson (b) (4)	21 Aug 2020 18:28:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:10:06
User closed query 'Per DM CLR: Indication = SUPPLEMENT, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:37:49
Query 'Per DM CLR: Indication = SUPPLEMENT, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate.' answered with 'Prophylaxis has been updated to yes' (Site from DM).	Erika Faust (b) (4) (b) (4)	16 Nov 2020 14:26:04
Signature has been broken.	Erika Faust (b) (4) (b) (4)	16 Nov 2020 14:25:50
User entered 'Yes (Y)' reason for change: Per Query Resolution	Erika Faust (b) (4) (b) (4)	16 Nov 2020 14:25:50
User opened query 'Per DM CLR: Indication = SUPPLEMENT, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 09:29:16
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 18:28:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Supplement'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:28:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query "" Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. " ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	09 Oct 2020 08:38:03
Query "" Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. " ' answered with 'Dose updated.' (Site from DM). Signature has been broken.	David Diemert (b) (4) (b) (4) David Diemert (b) (4) (b) (4)	08 Oct 2020 02:52:08 07 Oct 2020 22:16:47
User entered '1000' reason for change: New Information User opened query "" Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. " ' (Site from DM). User signature succeeded.	David Diemert (b) (4) (b) (4) David Diemert (b) (4) (b) (4) (b) (4), (b) (6)	07 Oct 2020 22:16:25 07 Oct 2020 22:16:25 05 Oct 2020 09:48:14
User entered '1' reason for change: Data Entry Error	David Diemert (b) (4) (b) (4) Hannah Yellin (b) (4) (b) (4)	27 Aug 2020 15:36:36 25 Aug 2020 20:05:38
User entered 'un'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 18:28:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
Signature has been broken.	David Diemert (b) (4)	07 Oct 2020 22:16:25
User entered 'IU (IU)' reason for change: New Information	David Diemert (b) (4)	07 Oct 2020 22:16:25
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'tablet (TABLET)' reason for change: Data Entry Error	Hannah Yellin (b) (4)	25 Aug 2020 20:05:38
User entered 'Other (OTHER)'	Taylor Ladson (b) (4)	21 Aug 2020 18:28:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty; reason for change Data Entry Error	(b) (4) Hannah Yellin (b) (4)	25 Aug 2020 20:05:38
User entered 'unknown'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:28:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'once daily (QD)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:28:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:28:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:28:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:28:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'un UNK 2012'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:28:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:28:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:28:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:28:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:28:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	21 Aug 2020 18:28:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Aug 2020 18:28:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 18:28:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Aug 2020 05:51:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 05:51:30
Data point term sent to Coder	System	21 Aug 2020 18:30:05
User entered 'Pantapropazole'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 18:29:49

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:29:49

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Gastroesophageal reflux disease'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:29:49

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query "" Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. " ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 08:35:12
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
Query "" Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. " ' answered with 'Dose updated' (Site from DM).	David Diemert (b) (4)	07 Oct 2020 22:15:35
Signature has been broken.	David Diemert (b) (4)	07 Oct 2020 22:15:25
User entered '20' reason for change: New Information	David Diemert (b) (4)	07 Oct 2020 22:15:25
User opened query "" Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. " ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 09:50:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '1' reason for change: Data Entry Error	Hannah Yellin (b) (4)	25 Aug 2020 20:06:11
User entered 'UN'	Taylor Ladson (b) (4)	21 Aug 2020 18:29:49

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User		Time (GMT)
User signature succeeded.	David Diemert	(b) (4)	08 Oct 2020 02:52:08
	(b) (4)		
Signature has been broken.	David Diemert	(b) (4)	07 Oct 2020 22:15:25
	(b) (4)		
User entered 'mg (mg)' reason for change: New Information	David Diemert	(b) (4)	07 Oct 2020 22:15:25
	(b) (4)		
User signature succeeded.	David Diemert	(b) (4)	27 Aug 2020 15:36:36
	(b) (4)		
User entered 'tablet (TABLET)' reason for change: Data Entry Error	Hannah Yellin	(b) (4)	25 Aug 2020 20:06:11
	(b) (4)		
User entered 'Other (OTHER)'	Taylor Ladson	(b) (4)	21 Aug 2020 18:29:49
	(b) (4)		

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty; reason for change Data Entry Error	(b) (4) Hannah Yellin (b) (4)	25 Aug 2020 20:06:11
User entered 'unknown'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:29:49

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'other (OTHER)' reason for change:	(b) (4)	
Data Entry Error	Hannah Yellin (b) (4)	25 Aug 2020 20:06:11
User entered 'once daily (QD)'	(b) (4)	
	Taylor Ladson (b) (4)	21 Aug 2020 18:29:49
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:08

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Every morning' reason for change:	(b) (4)	
Data Entry Error	Hannah Yellin (b) (4)	25 Aug 2020 20:06:11
User entered empty.	(b) (4)	
	Taylor Ladson (b) (4)	21 Aug 2020 18:29:49
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:29:49

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:29:49

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'un UNK 2018'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:29:49

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:29:49

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:29:49

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:29:49

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:29:49

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 20:06:11
User entered '1'	System	21 Aug 2020 18:29:49

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 20:06:11
User entered '1'	System	21 Aug 2020 18:29:49

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 20:06:11
User entered '804 (804)'	System	21 Aug 2020 18:29:49

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:08

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 13:48:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Oct 2020 13:48:12
Data point term sent to Coder	System	23 Oct 2020 13:42:20
Coding entries removed.	Elissa Malkin (b) (4) (b) (4)	23 Oct 2020 13:41:32
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:36:36
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 18:32:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Aug 2020 18:32:23
Data point term sent to Coder	System	21 Aug 2020 18:31:06
User entered 'Celebrex'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 18:30:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:30:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS(e.g. reumathoid, osteo). Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	28 Oct 2020 05:26:37
Query 'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS(e.g. reumathoid, osteo). Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'updated' (Site from DM). Signature has been broken.	David Diemert (b) (4) (b) (4) Elissa Malkin (b) (4) (b) (4)	23 Oct 2020 13:45:37 23 Oct 2020 13:41:42
User entered 'osteoARTHRITIS' reason for change: Per Query Resolution	Elissa Malkin (b) (4) (b) (4)	23 Oct 2020 13:41:32
User opened query 'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS(e.g. reumathoid, osteo). Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM). Query "'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS(e.g. reumathoid, osteo). Please reconcile with the AE and Med History eCRFs as appropriate. Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. " ' canceled (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 03:44:51
User opened query "'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS(e.g. reumathoid, osteo). Please reconcile with the AE and Med History eCRFs as appropriate. Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. " ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	23 Oct 2020 03:35:22
User entered 'Arthritis'	David Diemert (b) (4) (b) (4) Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 15:36:36 21 Aug 2020 18:30:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Jan 2021 03:20:07
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Jan 2021 05:06:30
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'Data entry error.' (Site from DM).	David Diemert (b) (4) (b) (4)	03 Jan 2021 17:36:44
Signature has been broken.	David Diemert (b) (4) (b) (4)	03 Jan 2021 17:36:32
User entered '200' reason for change: Data Entry Error	David Diemert (b) (4) (b) (4)	03 Jan 2021 17:36:32
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 18:00:43
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 08:35:32
User signature succeeded.	David Diemert (b) (4) (b) (4)	08 Oct 2020 02:52:08
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'Dose updated.' (Site from DM).	David Diemert (b) (4) (b) (4)	07 Oct 2020 22:18:09
Signature has been broken.	David Diemert (b) (4) (b) (4)	07 Oct 2020 22:18:02
User entered '20' reason for change: New Information	David Diemert (b) (4) (b) (4)	07 Oct 2020 22:18:02
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 09:50:45

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '1' reason for change: Data Entry Error	(b) (4) Hannah Yellin (b) (4)	25 Aug 2020 20:06:32
User entered 'un'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:30:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User		Time (GMT)
User signature succeeded.	David Diemert	(b) (4)	08 Oct 2020 02:52:08
	(b) (4)		
Signature has been broken.	David Diemert	(b) (4)	07 Oct 2020 22:18:02
	(b) (4)		
User entered 'mg (mg)' reason for change: New Information	David Diemert	(b) (4)	07 Oct 2020 22:18:02
	(b) (4)		
User signature succeeded.	David Diemert	(b) (4)	27 Aug 2020 15:36:36
	(b) (4)		
User entered 'tablet (TABLET)' reason for change: Data Entry Error	Hannah Yellin	(b) (4)	25 Aug 2020 20:06:32
	(b) (4)		
User entered 'Other (OTHER)'	Taylor Ladson	(b) (4)	21 Aug 2020 18:30:29
	(b) (4)		

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty; reason for change Data Entry Error	(b) (4) Hannah Yellin (b) (4)	25 Aug 2020 20:06:32
User entered 'unknown'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:30:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'once daily (QD)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:30:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:30:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:30:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:30:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'un Mar 2020'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:30:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:30:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:30:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:30:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:30:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	21 Aug 2020 18:30:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Aug 2020 18:30:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 18:30:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 18:34:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 18:34:10
Data point term sent to Coder	System	21 Aug 2020 18:32:10
User entered 'Aspirin'	Taylor Ladson (b) (4)	21 Aug 2020 18:32:01

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:32:01

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'cardioprotective'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:32:01

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '81'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:32:01

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'mg (mg)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:32:01

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:32:01

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'once daily (QD)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:32:01

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:32:01

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:32:01

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:32:01

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'un Jul 2018'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:32:01

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:32:01

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:32:01

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:32:01

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:32:01

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	21 Aug 2020 18:32:01

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	21 Aug 2020 18:32:01

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 18:32:01

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: SUMATRIPTAN, PRODUCTSYNONYM: IMITREX [SUMATRIPTAN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	26 Aug 2020 08:17:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 08:17:46
Data point term sent to Coder	System	21 Aug 2020 18:34:14
User entered 'imitrex'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 18:33:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:33:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'migraine headache'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:33:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query "" Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. " ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	12 Oct 2020 05:37:18
Query "" Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. " ' answered with 'Dose updated.' (Site from DM). Signature has been broken.	David Diemert (b) (4) (b) (4) David Diemert (b) (4) (b) (4)	08 Oct 2020 02:52:08 07 Oct 2020 22:19:26
User entered '25' reason for change: New Information User opened query "" Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. " ' (Site from DM). User signature succeeded.	David Diemert (b) (4) (b) (4) David Diemert (b) (4) (b) (4) (b) (4), (b) (6)	07 Oct 2020 22:19:19 07 Oct 2020 22:19:19 05 Oct 2020 08:31:15
User entered '1' reason for change: Data Entry Error	David Diemert (b) (4) (b) (4) Hannah Yellin (b) (4)	27 Aug 2020 15:36:36 25 Aug 2020 20:07:09
User entered 'un'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 18:33:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:52:08
Signature has been broken.	David Diemert (b) (4)	07 Oct 2020 22:19:19
User entered 'mg (mg)' reason for change: New Information	David Diemert (b) (4)	07 Oct 2020 22:19:19
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'tablet (TABLET)' reason for change: Data Entry Error	Hannah Yellin (b) (4)	25 Aug 2020 20:07:09
User entered 'Other (OTHER)'	Taylor Ladson (b) (4)	21 Aug 2020 18:33:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty; reason for change Data Entry Error	(b) (4) Hannah Yellin (b) (4)	25 Aug 2020 20:07:09
User entered 'unknown'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:33:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'as needed (PRN)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:33:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:33:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:33:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:33:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'un UNK 1998'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:33:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:08

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:33:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:33:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:33:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:33:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 18:33:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 18:33:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 18:33:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:08

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Aug 2020 18:33:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Aug 2020 18:33:05
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
Data point term sent to Coder	System	25 Aug 2020 13:56:50
User closed query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	System	25 Aug 2020 13:56:47
Query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' answered with 'Active ingredients added to medication name' (Site from System).	Hannah Yellin (b) (4)	25 Aug 2020 13:56:47
User entered 'EXCEDRIN [Acetaminophen/Aspirin/Caffeine]' reason for change: Per Query Resolution	Hannah Yellin (b) (4)	25 Aug 2020 13:56:34
User opened query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	Coder Import (b) (4)	24 Aug 2020 13:23:30
Data point term sent to Coder	System	21 Aug 2020 18:34:18
User entered 'Excedrin'	Taylor Ladson (b) (4)	21 Aug 2020 18:33:54

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:33:54

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'migraine headache'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:33:54

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '2'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:33:54

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'tablet (TABLET)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:33:54

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:33:54

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'as needed (PRN)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:33:54

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:33:54

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:33:54

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:33:54

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'un UNK 1998'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:33:54

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:33:54

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:33:54

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:33:54

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:33:54

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 18:33:54

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 18:33:54

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 18:33:54

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Aug 2020 18:36:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 18:36:17
Data point term sent to Coder	System	21 Aug 2020 18:35:22
User entered 'Zyrtec'	Taylor Ladson (b) (4)	21 Aug 2020 18:34:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:34:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'seasonal allergies'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:34:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '1' reason for change: Data Entry Error	(b) (4) Hannah Yellin (b) (4)	25 Aug 2020 20:07:39
User entered 'un'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:34:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'tablet (TABLET)' reason for change:	(b) (4)	
Data Entry Error	Hannah Yellin (b) (4)	25 Aug 2020 20:07:39
User entered 'Other (OTHER)'	(b) (4)	
	Taylor Ladson (b) (4)	21 Aug 2020 18:34:38
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty; reason for change Data Entry Error	(b) (4) Hannah Yellin (b) (4)	25 Aug 2020 20:07:39
User entered 'unknown'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:34:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'as needed (PRN)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:34:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:34:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:34:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:34:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'un UNK 2015'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:34:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:34:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:34:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:34:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:34:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 18:34:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 18:34:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 18:34:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Aug 2020 18:36:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 18:36:17
Data point term sent to Coder	System	21 Aug 2020 18:35:28
User entered 'Flonase'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 18:35:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:35:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'seasonal allergies'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:35:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '1' reason for change: Data Entry Error	(b) (4) Hannah Yellin (b) (4)	25 Aug 2020 20:07:58
User entered 'un'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:35:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Other (OTHER)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:35:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Spray' reason for change: Data Entry Error	(b) (4) Hannah Yellin (b) (4)	25 Aug 2020 20:07:58
User entered 'unknown'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:35:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'as needed (PRN)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:35:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:35:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Nasal (NASAL)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:35:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:35:24
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'un UNK 2015'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:35:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:35:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:35:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:35:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 18:35:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 18:35:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 18:35:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 18:35:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:36
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 11:00:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 11:00:20
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 23:07:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 23:07:48
Data point term sent to Coder	System	22 Sep 2020 15:01:28
Coding entries removed.	Hannah Yellin (b) (4)	22 Sep 2020 15:00:33
Coding entries removed.	Hannah Yellin (b) (4)	22 Sep 2020 15:00:33
Signature has been broken.	Hannah Yellin (b) (4)	22 Sep 2020 15:00:33
User entered 'Dexamethasone' reason for change: New Information	Hannah Yellin (b) (4)	22 Sep 2020 15:00:33

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:08

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Sep 2020 06:29:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Sep 2020 06:29:37
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
Data point term sent to Coder	System	08 Sep 2020 18:32:00
User entered 'Prednisone'	Hannah Yellin (b) (4)	08 Sep 2020 18:31:27

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:36
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	08 Sep 2020 18:31:27
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:36
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
Signature has been broken.	Hannah Yellin (b) (4)	22 Sep 2020 15:00:33
User entered 'Cellulitis' reason for change: New Information	Hannah Yellin (b) (4)	22 Sep 2020 15:00:33
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered 'Left knee inflammation'	Hannah Yellin (b) (4)	08 Sep 2020 18:31:27

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:36
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
Signature has been broken.	Hannah Yellin (b) (4)	22 Sep 2020 15:00:33
User entered '1.5' reason for change: New Information	Hannah Yellin (b) (4)	22 Sep 2020 15:00:33
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered '6'	Hannah Yellin (b) (4)	08 Sep 2020 18:31:27

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:36
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
Signature has been broken.	Hannah Yellin (b) (4)	22 Sep 2020 15:00:33
User entered 'mg (mg)' reason for change: New Information	Hannah Yellin (b) (4)	22 Sep 2020 15:00:33
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered 'Other (OTHER)'	Hannah Yellin (b) (4)	08 Sep 2020 18:31:27

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:36
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
Signature has been broken.	Hannah Yellin (b) (4)	22 Sep 2020 15:00:33
User entered empty; reason for change New Information	Hannah Yellin (b) (4)	22 Sep 2020 15:00:33
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered 'Dose pack'	Hannah Yellin (b) (4)	08 Sep 2020 18:31:27

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:36
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
Signature has been broken.	Hannah Yellin (b) (4)	22 Sep 2020 15:00:33
User entered 'other (OTHER)' reason for change: New Information	Hannah Yellin (b) (4)	22 Sep 2020 15:00:33
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered 'unknown (UNKNOWN)'	Hannah Yellin (b) (4)	08 Sep 2020 18:31:27

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:36
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
Signature has been broken.	Hannah Yellin (b) (4)	22 Sep 2020 15:00:33
User entered '6-day taper' reason for change: New Information	Hannah Yellin (b) (4)	22 Sep 2020 15:00:33
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered empty.	Hannah Yellin (b) (4)	08 Sep 2020 18:31:27

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:36
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
Signature has been broken.	Hannah Yellin (b) (4)	22 Sep 2020 15:00:33
User entered 'Oral (ORAL)' reason for change: New Information	Hannah Yellin (b) (4)	22 Sep 2020 15:00:33
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered 'Other (OTHER)'	Hannah Yellin (b) (4)	08 Sep 2020 18:31:27

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:36
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
Signature has been broken.	Hannah Yellin (b) (4)	22 Sep 2020 15:00:33
User entered empty; reason for change New Information	Hannah Yellin (b) (4)	22 Sep 2020 15:00:33
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered 'Unknown'	Hannah Yellin (b) (4)	08 Sep 2020 18:31:27

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:36
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered '29 Aug 2020'	(b) (4) Hannah Yellin (b) (4)	08 Sep 2020 18:31:27
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:36
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	08 Sep 2020 18:31:27

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:36
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
Signature has been broken.	Hannah Yellin (b) (4)	22 Sep 2020 15:00:33
User entered 'No (N)' reason for change: New Information	Hannah Yellin (b) (4)	22 Sep 2020 15:00:33
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered 'Yes (Y)'	Hannah Yellin (b) (4)	08 Sep 2020 18:31:27

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:36
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
Signature has been broken.	Hannah Yellin (b) (4)	22 Sep 2020 15:00:33
User entered '03 Sep 2020' reason for change: New Information	Hannah Yellin (b) (4)	22 Sep 2020 15:00:33
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered empty.	Hannah Yellin (b) (4)	08 Sep 2020 18:31:27

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:36
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:41:06
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	08 Sep 2020 18:31:27
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:36
User entered empty.	System	08 Sep 2020 18:31:27

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:36
User entered empty.	System	08 Sep 2020 18:31:27

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:36
User entered empty.	System	08 Sep 2020 18:31:27

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:38
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Sep 2020 05:55:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Sep 2020 05:55:54
Data point term sent to Coder	System	14 Sep 2020 17:10:42
User entered 'Ondansetron'	Madhu Balachandran (b) (4)	14 Sep 2020 17:10:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:38
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:10:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:38
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered 'Gastroenteritis (Associated Nausea)'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:10:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:38
User signature succeeded.	David Diemert (b) (4)	08 Jan 2021 03:20:07
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Jan 2021 05:07:59
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'Corrected.' (Site from DM).	David Diemert (b) (4) (b) (4)	03 Jan 2021 17:39:25
Signature has been broken.	David Diemert (b) (4) (b) (4)	03 Jan 2021 17:39:17
User entered '8' reason for change: New Information	David Diemert (b) (4) (b) (4)	03 Jan 2021 17:39:17
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 18:01:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 19:32:04
Signature has been broken.	Erika Faust (b) (4) (b) (4)	02 Nov 2020 14:30:28
User entered '5' reason for change: Data Entry Error	Erika Faust (b) (4) (b) (4)	02 Nov 2020 14:30:28
User signature succeeded.	David Diemert (b) (4) (b) (4)	17 Sep 2020 04:15:17
User entered '4'	Madhu Balachandran (b) (4)	14 Sep 2020 17:10:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:38
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered 'mg (mg)'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:10:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:38
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:10:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:38
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered 'once daily (QD)'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:10:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:38
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:10:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:38
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered 'Oral (ORAL)'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:10:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:38
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:10:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:38
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered '04 Sep 2020'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:10:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:38
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:10:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:38
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:10:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:38
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered '04 Sep 2020'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:10:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:38
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:10:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:38
User entered 'I'	System	14 Sep 2020 17:10:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:38
User entered 'I'	System	14 Sep 2020 17:10:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:38
User entered '804 (804)'	System	14 Sep 2020 17:10:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 17:12:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 17:12:44
Data point term sent to Coder	System	14 Sep 2020 17:11:45
User entered 'Tylenol'	Madhu Balachandran (b) (4)	14 Sep 2020 17:11:17

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:11:17

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered 'Gastroenteritis (Associated Headache)'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:11:17

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 19:32:04
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	02 Nov 2020 14:30:58
User entered '1000' reason for change: Data Entry Error	(b) (4)	
	Erika Faust (b) (4)	02 Nov 2020 14:30:58
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered '500'	(b) (4)	
	Madhu Balachandran	14 Sep 2020 17:11:17
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered 'mg (mg)'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:11:17

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:11:17

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 19:32:04
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	02 Nov 2020 14:30:58
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4)	
	Erika Faust (b) (4)	02 Nov 2020 14:30:58
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered 'twice daily (BID)'	(b) (4)	
	Madhu Balachandran	14 Sep 2020 17:11:17
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:11:17

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered 'Oral (ORAL)'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:11:17

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:11:17

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered '05 Sep 2020'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:11:17

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:11:17

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:11:17

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered '05 Sep 2020'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:11:17

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:15:17
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	14 Sep 2020 17:11:17

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User entered empty.	System	02 Nov 2020 14:30:58
User entered '2'	System	14 Sep 2020 17:11:17

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User entered empty.	System	02 Nov 2020 14:30:58
User entered '1'	System	14 Sep 2020 17:11:17

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User entered empty.	System	02 Nov 2020 14:30:58
User entered '804 (804)'	System	14 Sep 2020 17:11:17

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:59
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANTIHISTAMINES FOR TOPICAL USE, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 15:30:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 15:30:46
Data point term sent to Coder	System	22 Sep 2020 15:03:38
User entered 'Benadryl 2% cream'	Hannah Yellin (b) (4)	22 Sep 2020 15:03:19

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:59
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 15:03:19
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:59
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'Insect bites'	Hannah Yellin (b) (4)	22 Sep 2020 15:03:19

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:59
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'l'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 15:03:19

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:59
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'Other (OTHER)'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 15:03:19

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:59
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'Application'	(b) (4) Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 15:03:19

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:59
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'four times daily (QID)'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 15:03:19

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:59
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered empty.	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 15:03:19

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:59
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'Topical (TOPICAL)'	Hannah Yellin (b) (4)	22 Sep 2020 15:03:19

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:59
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered empty.	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 15:03:19
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:59
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered '28 Aug 2020'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 15:03:19
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:59
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 15:03:19

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:59
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 15:03:19

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:59
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered '28 Aug 2020'	Hannah Yellin (b) (4)	22 Sep 2020 15:03:19

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:59
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 15:03:19

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:59
User entered '4'	System	22 Sep 2020 15:03:19

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:59
User entered 'I'	System	22 Sep 2020 15:03:19

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:59
User entered '804 (804)'	System	22 Sep 2020 15:03:19

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIM DS - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Sep 2020 17:19:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Sep 2020 17:19:49
Data point term sent to Coder	System	22 Sep 2020 17:18:57
User entered 'Bactrim DS' reason for change: Data Entry Error	Madhu Balachandran (b) (4)	22 Sep 2020 17:18:33
Data point term sent to Coder	System	22 Sep 2020 15:04:40
User entered 'Antibiotic (unknown)'	Hannah Yellin (b) (4)	22 Sep 2020 15:03:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 15:03:58
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'Cellulitis'	(b) (4) Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 15:03:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered '2' reason for change: Data Entry Error	(b) (4)	
	Madhu Balachandran	22 Sep 2020 17:18:33
User entered '1'	(b) (4)	
	Hannah Yellin (b) (4)	22 Sep 2020 15:03:58
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'tablet (TABLET)'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 15:03:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered empty.	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 15:03:58
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'twice daily (BID)' reason for change:	(b) (4)	
Data Entry Error	Madhu Balachandran	22 Sep 2020 17:18:33
User entered 'once daily (QD)'	(b) (4)	
	Hannah Yellin (b) (4)	22 Sep 2020 15:03:58
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered empty.	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 15:03:58
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'Oral (ORAL)'	Hannah Yellin (b) (4)	22 Sep 2020 15:03:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered empty.	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 15:03:58
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered '29 Aug 2020'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 15:03:58
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered '0'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 15:03:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'No (N)'	Hannah Yellin (b) (4)	22 Sep 2020 15:03:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered '07 Sep 2020'	Hannah Yellin (b) (4)	22 Sep 2020 15:03:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 15:03:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User entered '2'	System	22 Sep 2020 17:18:33
User entered '1'	System	22 Sep 2020 15:03:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User entered 'I'	System	22 Sep 2020 15:03:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User entered '804 (804)'	System	22 Sep 2020 15:03:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:23
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, WEAK (GROUP I), PRODUCT: HYDROCORTISONE, PRODUCTSYNONYM: CORTISONE [HYDROCORTISONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 09:18:55
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 Apr 2021 09:18:55
User coded data point as ATC: VARIOUS, ATC: HOMEOPATHIC PREPARATION, PRODUCT: CORTISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 12:05:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 12:05:35
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:14:04
Data point term sent to Coder	System	22 Sep 2020 15:04:44
User entered 'Cortisone 1% cream'	Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 15:04:27

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 15:04:27

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'Cellulitis'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 15:04:27

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'l'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 15:04:27
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'Other (OTHER)'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 15:04:27

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'Application'	(b) (4) Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 15:04:27

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'twice daily (BID)'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 15:04:27
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 15:04:27

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'Topical (TOPICAL)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 15:04:27

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered empty.	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 15:04:27
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered '29 Aug 2020'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 15:04:27

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered '0'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 15:04:27

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 15:04:27

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered '03 Sep 2020'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 15:04:27
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:23
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:14:04
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	22 Sep 2020 15:04:27

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:23
User entered '2'	System	22 Sep 2020 15:04:27

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:23
User entered '1'	System	22 Sep 2020 15:04:27

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:23
User entered '804 (804)'	System	22 Sep 2020 15:04:27

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:07
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Sep 2020 19:53:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Sep 2020 19:53:48
Data point term sent to Coder	System	25 Sep 2020 18:50:52
User entered 'clindamycin'	Taylor Ladson (b) (4)	25 Sep 2020 18:50:00

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:07
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:17
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	25 Sep 2020 18:50:00

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:07
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:17
User entered 'prophylaxis for dental work'	(b) (4) Taylor Ladson (b) (4)	25 Sep 2020 18:50:00

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:07
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:17
User entered '600'	(b) (4) Taylor Ladson (b) (4)	25 Sep 2020 18:50:00

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:07
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:17
User entered 'mg (mg)'	(b) (4) Taylor Ladson (b) (4)	25 Sep 2020 18:50:00

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:07
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:17
User entered empty.	(b) (4) Taylor Ladson (b) (4)	25 Sep 2020 18:50:00
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:07
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:17
User entered 'once (ONCE)'	(b) (4) Taylor Ladson (b) (4)	25 Sep 2020 18:50:00

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:07
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:17
User entered empty.	(b) (4) Taylor Ladson (b) (4)	25 Sep 2020 18:50:00
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:07
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:17
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4)	25 Sep 2020 18:50:00

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:07
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:17
User entered empty.	(b) (4) Taylor Ladson (b) (4)	25 Sep 2020 18:50:00
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:07
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:17
User entered '23 Sep 2020'	(b) (4) Taylor Ladson (b) (4)	25 Sep 2020 18:50:00

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:07
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:17
User entered '0'	(b) (4) Taylor Ladson (b) (4)	25 Sep 2020 18:50:00
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:07
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:17
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	25 Sep 2020 18:50:00

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:07
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:17
User entered '23 Sep 2020'	(b) (4) Taylor Ladson (b) (4)	25 Sep 2020 18:50:00
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:07
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:17
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	25 Sep 2020 18:50:00

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:07
User entered empty.	System	25 Sep 2020 18:50:00

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:07
User entered empty.	System	25 Sep 2020 18:50:00

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:07
User entered empty.	System	25 Sep 2020 18:50:00

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:08

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:27
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:30:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Feb 2021 00:47:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Feb 2021 00:47:34
Data point term sent to Coder	System	02 Feb 2021 19:54:56
Coding entries removed.	Elissa Malkin (b) (4)	02 Feb 2021 19:54:48
Signature has been broken.	Elissa Malkin (b) (4)	02 Feb 2021 19:54:48
User entered 'HYDROCODONE/Acetaminophen' reason for change: Per Query Resolution	Elissa Malkin (b) (4)	02 Feb 2021 19:54:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Nov 2020 06:28:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Nov 2020 06:28:50
Data point term sent to Coder	System	17 Nov 2020 21:18:21
Coding entries removed.	Elissa Malkin (b) (4)	17 Nov 2020 21:17:57
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:26:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 20:55:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:08

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'Hydrocodone'	Coder Import (b) (4) (b) (4) System Erika Faust (b) (4) (b) (4)	02 Oct 2020 20:55:53 02 Oct 2020 20:05:43 02 Oct 2020 20:04:47

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:27
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:26:49
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 20:04:47

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:27
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and confirm if this is given for AE condition #8. If yes, please update Con Med start and stop date to reflect a match with AE #8. Otherwise, add an AE condition that reflects this Con Med indication within its time frame as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 09:00:34
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and confirm if this is given for AE condition #8. If yes, please update Con Med start and stop date to reflect a match with AE #8. Otherwise, add an AE condition that reflects this Con Med indication within its time frame as appropriate. ' answered with 'A con procedure was done on 23EP2020 for which this con med was used. The con procedure was due to underlying past medical history ' (Site from DM).	Elissa Malkin (b) (4) (b) (4)	08 Mar 2021 19:51:28
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and confirm if this is given for AE condition #8. If yes, please update Con Med start and stop date to reflect a match with AE #8. Otherwise, add an AE condition that reflects this Con Med indication within its time frame as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 02:24:57
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, rather than the drug class or 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)	20 Nov 2020 09:04:09
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:10:06

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
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 drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'updated' (Site from DM). Signature has been broken.	Elissa Malkin (b) (4) (b) (4)	17 Nov 2020 21:18:04
	Elissa Malkin (b) (4)	17 Nov 2020 21:17:57
User entered 'PAIN MANAGEMENT secondary to dental work' reason for change: Per Query Resolution	Elissa Malkin (b) (4) (b) (4)	17 Nov 2020 21:17:57
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, rather than the drug class or 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). User signature succeeded.	(b) (4), (b) (6) David Diemert (b) (4) (b) (4)	16 Nov 2020 09:31:20
	Erika Faust (b) (4) (b) (4)	03 Oct 2020 15:26:49
User entered 'Pain management'		02 Oct 2020 20:04:47

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:27
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:30:01
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication (e.g., 10, 15, 20, 30). Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 09:09:58
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication (e.g., 10, 15, 20, 30). Please correct the dosage or provide explanation for alternate dosage. ' answered with 'updated' (Site from DM).	Elissa Malkin (b) (4)	02 Feb 2021 19:54:55
Signature has been broken.	(b) (4)	02 Feb 2021 19:54:48
User entered '5/325' reason for change: Per Query Resolution	Elissa Malkin (b) (4)	02 Feb 2021 19:54:48
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication (e.g., 10, 15, 20, 30). Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 06:44:58
User signature succeeded.	David Diemert (b) (4)	08 Jan 2021 03:20:07
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 05:30:57
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'Updated.' (Site from DM).	David Diemert (b) (4)	03 Jan 2021 17:42:30
Signature has been broken.	David Diemert (b) (4)	03 Jan 2021 17:42:24
User entered '5' reason for change: New Information	David Diemert (b) (4)	03 Jan 2021 17:42:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4)	30 Dec 2020 18:02:20
	David Diemert (b) (4) (b) (4)	03 Oct 2020 15:26:49
User entered 'l'	Erika Faust (b) (4) (b) (4)	02 Oct 2020 20:04:47

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:27
User signature succeeded.	David Diemert (b) (4)	08 Jan 2021 03:20:07
Signature has been broken.	David Diemert (b) (4)	03 Jan 2021 17:42:24
User entered 'mg (mg)' reason for change: New Information	David Diemert (b) (4)	03 Jan 2021 17:42:24
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:26:49
User entered 'tablet (TABLET)'	Erika Faust (b) (4)	02 Oct 2020 20:04:47

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:27
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:26:49
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 20:04:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:27
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:26:49
User entered 'once daily (QD)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 20:04:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:27
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:26:49
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 20:04:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:27
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:26:49
User entered 'Oral (ORAL)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 20:04:47

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:27
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:26:49
User entered empty.	(b) (4) Erika Faust (b) (4)	02 Oct 2020 20:04:47

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:27
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:26:49
User entered '25 Sep 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 20:04:47

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:27
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:26:49
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 20:04:47

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:27
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:26:49
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 20:04:47

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:27
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:26:49
User entered '27 Sep 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 20:04:47

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:27
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:26:49
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 20:04:47

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:27
User entered 'I'	System	02 Oct 2020 20:04:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:27
User entered 'I'	System	02 Oct 2020 20:04:47

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:27
User entered '804 (804)'	System	02 Oct 2020 20:04:47

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 21:34:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 21:34:51
Data point term sent to Coder Coding entries removed.	System Elissa Malkin (b) (4)	17 Nov 2020 21:19:22 17 Nov 2020 21:18:33
User signature succeeded.	(b) (4) David Diemert (b) (4)	(b) (4) 03 Oct 2020 15:26:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 20:06:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 20:06:50
Data point term sent to Coder User entered 'Tylenol'	System Erika Faust (b) (4)	02 Oct 2020 20:05:44 02 Oct 2020 20:05:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:20
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:26:49
User entered 'No (N)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 20:05:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:20
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, rather than the drug class or 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). User signature succeeded.	(b) (4), (b) (6) David Diemert (b) (4)	20 Nov 2020 09:04:21 20 Nov 2020 04:10:06
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 drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'updated' (Site from DM). Signature has been broken.	Elissa Malkin (b) (4) Elissa Malkin (b) (4)	17 Nov 2020 21:18:40 17 Nov 2020 21:18:33
User entered 'PAIN MANAGEMENT secondary to dental work' reason for change: Per Query Resolution	Elissa Malkin (b) (4) Elissa Malkin (b) (4)	17 Nov 2020 21:18:33
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 drug class or 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). User signature succeeded.	(b) (4), (b) (6) David Diemert (b) (4)	16 Nov 2020 09:31:36 03 Oct 2020 15:26:49
User entered 'Pain management'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 20:05:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:20
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:26:49
User entered '1000'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 20:05:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:20
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:26:49
User entered 'mg (mg)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 20:05:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:20
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:26:49
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 20:05:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:20
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:26:49
User entered 'once daily (QD)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 20:05:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:20
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:26:49
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 20:05:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:20
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:26:49
User entered 'Oral (ORAL)'	(b) (4) Erika Faust (b) (4)	02 Oct 2020 20:05:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:20
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:26:49
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 20:05:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:20
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:26:49
User entered '23 Sep 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 20:05:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:20
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:26:49
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 20:05:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:20
User signature succeeded.	David Diemert (b) (4)	08 Jan 2021 03:20:07
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) (4), (b) (6)	04 Jan 2021 05:32:56
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)	03 Jan 2021 17:45:11
Signature has been broken.	David Diemert (b) (4) (b) (4)	03 Jan 2021 17:45:05
User entered 'No (N)' reason for change: New Information	David Diemert (b) (4) (b) (4)	03 Jan 2021 17:45:05
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)	30 Dec 2020 18:35:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Oct 2020 15:26:49
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	02 Oct 2020 20:05:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:20
User signature succeeded.	David Diemert (b) (4)	08 Jan 2021 03:20:07
Signature has been broken.	David Diemert (b) (4)	03 Jan 2021 17:45:05
User entered '27 Sep 2020' reason for change: New Information	David Diemert (b) (4)	03 Jan 2021 17:45:05
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:26:49
User entered empty.	Erika Faust (b) (4)	02 Oct 2020 20:05:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:20
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:26:49
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	02 Oct 2020 20:05:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:20
User entered 'I'	System	02 Oct 2020 20:05:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:20
User entered 'I'	System	02 Oct 2020 20:05:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:20
User entered '804 (804)'	System	02 Oct 2020 20:05:34

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:39
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 19:26:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 19:26:44
Data point term sent to Coder	System	22 Oct 2020 16:17:20
User entered 'Azithromycin'	Erika Faust (b) (4)	22 Oct 2020 16:16:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:39
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:16:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:39
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered 'Dental work prophylaxis'	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:16:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:39
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered '500'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:16:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:39
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered 'mg (mg)'	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:16:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:39
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:16:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:39
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered 'once (ONCE)'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:16:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:39
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:16:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:39
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered 'Oral (ORAL)'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:16:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:39
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered empty.	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:16:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:39
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered '19 Oct 2020'	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:16:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:39
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:16:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:39
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:16:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:39
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered '19 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:16:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:39
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:16:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:39
User entered empty.	System	22 Oct 2020 16:16:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:39
User entered empty.	System	22 Oct 2020 16:16:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:39
User entered empty.	System	22 Oct 2020 16:16:24

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 21:06:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 21:06:31
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
Data point term sent to Coder	System (b) (4)	22 Oct 2020 16:18:24
User entered 'Excedrin (250/250/65 mg)'	Erika Faust (b) (4)	22 Oct 2020 16:17:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:45
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered 'No (N)'	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:17:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:45
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered 'Tooth pain'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:17:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:45
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered '2'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:17:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:45
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered 'tablet (TABLET)'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:17:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:45
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:17:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:45
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered 'once (ONCE)'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:17:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:45
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:17:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:45
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered 'Oral (ORAL)'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:17:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:45
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:17:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:45
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered '19 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:17:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:45
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:17:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:45
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:17:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:45
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered '19 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:17:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:45
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:17:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:45
User entered empty.	System	22 Oct 2020 16:17:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:45
User entered empty.	System	22 Oct 2020 16:17:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:45
User entered empty.	System	22 Oct 2020 16:17:38

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:51
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 16:20:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 16:20:31
Data point term sent to Coder	System	22 Oct 2020 16:19:25
User entered 'Tylenol'	Erika Faust (b) (4)	22 Oct 2020 16:18:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:51
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered 'No (N)'	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:18:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:51
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered 'Tooth pain'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:18:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:51
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered '650'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:18:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:51
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered 'mg (mg)'	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:18:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:51
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:18:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:51
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered 'once (ONCE)'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:18:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:51
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:18:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:51
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered 'Oral (ORAL)'	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:18:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:51
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:18:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:51
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered '19 Oct 2020'	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:18:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:51
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:18:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:51
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered 'No (N)'	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:18:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:51
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered '19 Oct 2020'	(b) (4) Erika Faust (b) (4)	22 Oct 2020 16:18:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:51
User signature succeeded.	David Diemert (b) (4)	23 Oct 2020 13:45:37
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	22 Oct 2020 16:18:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:51
User entered empty.	System	22 Oct 2020 16:18:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:51
User entered empty.	System	22 Oct 2020 16:18:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:51
User entered empty.	System	22 Oct 2020 16:18:29

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:57
User signature succeeded.	David Diemert (b) (4)	29 Oct 2020 03:21:13
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)	27 Oct 2020 19:43:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 19:43:36
Data point term sent to Coder	System	27 Oct 2020 19:42:23
User entered 'influenza vaccination'	DeEnna Wedding (b) (4)	27 Oct 2020 19:42:16

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:57
User signature succeeded.	David Diemert (b) (4)	29 Oct 2020 03:21:13
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	27 Oct 2020 19:42:16

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:57
User signature succeeded.	David Diemert (b) (4)	29 Oct 2020 03:21:13
User entered 'flu prevention'	(b) (4) DeEnna Wedding (b) (4)	27 Oct 2020 19:42:16

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:57
User signature succeeded.	David Diemert (b) (4)	29 Oct 2020 03:21:13
User entered '0.5'	(b) (4) DeEnna Wedding (b) (4)	27 Oct 2020 19:42:16

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:57
User signature succeeded.	David Diemert (b) (4)	29 Oct 2020 03:21:13
User entered 'mL (mL)'	(b) (4) DeEnna Wedding (b) (4)	27 Oct 2020 19:42:16

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:57
User signature succeeded.	David Diemert (b) (4)	29 Oct 2020 03:21:13
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	27 Oct 2020 19:42:16

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:57
User signature succeeded.	David Diemert (b) (4)	29 Oct 2020 03:21:13
User entered 'once (ONCE)'	(b) (4) DeEnna Wedding (b) (4)	27 Oct 2020 19:42:16

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:57
User signature succeeded.	David Diemert (b) (4)	29 Oct 2020 03:21:13
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	27 Oct 2020 19:42:16

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:57
User signature succeeded.	David Diemert (b) (4)	29 Oct 2020 03:21:13
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) DeEnna Wedding (b) (4)	27 Oct 2020 19:42:16

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:57
User signature succeeded.	David Diemert (b) (4)	29 Oct 2020 03:21:13
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	27 Oct 2020 19:42:16

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:57
User signature succeeded.	David Diemert (b) (4)	29 Oct 2020 03:21:13
User entered '09 Oct 2020'	(b) (4) DeEnna Wedding (b) (4)	27 Oct 2020 19:42:16

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:57
User signature succeeded.	David Diemert (b) (4)	29 Oct 2020 03:21:13
User entered '0'	(b) (4) DeEnna Wedding (b) (4)	27 Oct 2020 19:42:16

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:57
User signature succeeded.	David Diemert (b) (4)	29 Oct 2020 03:21:13
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	27 Oct 2020 19:42:16

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:57
User signature succeeded.	David Diemert (b) (4)	29 Oct 2020 03:21:13
User entered '09 Oct 2020'	(b) (4) DeEnna Wedding (b) (4)	27 Oct 2020 19:42:16

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:57
User signature succeeded.	David Diemert (b) (4)	29 Oct 2020 03:21:13
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4)	27 Oct 2020 19:42:16

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:57
User entered empty.	System	27 Oct 2020 19:42:16

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:57
User entered empty.	System	27 Oct 2020 19:42:16

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:57
User entered empty.	System	27 Oct 2020 19:42:16

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Mar 2021 18:17:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Mar 2021 18:17:56
Data point term sent to Coder	System	10 Mar 2021 18:17:06
User entered 'Tylenol'	Hannah Yellin (b) (4) (b) (4)	10 Mar 2021 18:16:45

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:16:45

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Pharyngitis'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:16:45

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '650'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:16:45

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'mg (mg)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:16:45

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered empty.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:16:45
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'twice daily (BID)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:16:45

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered empty.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:16:45

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Oral (ORAL)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:16:45

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered empty.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:16:45

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '07 Mar 2021'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:16:45

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:08

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '0'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:16:45

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:16:45

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered empty.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:16:45

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:16:45

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	10 Mar 2021 18:16:45

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Mar 2021 18:16:45

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Mar 2021 18:16:45

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:08

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN;DIPHENHYDRAMINE HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 02:20:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 02:20:52
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
Data point term sent to Coder	System	10 Mar 2021 18:18:07
User entered 'Acetaminophen/Diphenhydramine'	Hannah Yellin (b) (4)	10 Mar 2021 18:17:37

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:17:37

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Pharyngitis'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:17:37

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '500/25'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:17:37

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'mg (mg)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:17:37

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered empty.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:17:37
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'other (OTHER)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:17:37

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Every night at bedtime as needed'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:17:37

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Oral (ORAL)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:17:37

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered empty.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:17:37

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '06 Mar 2021'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:17:37

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:08

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '0'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:17:37
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:17:37

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered empty.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:17:37
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:17:37

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Mar 2021 18:17:37

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Mar 2021 18:17:37

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Mar 2021 18:17:37

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:08

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:29
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)	23 Mar 2021 20:17:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 20:17:44
Data point term sent to Coder Coding entries removed.	System David Diemert (b) (4) (b) (4)	23 Mar 2021 20:17:26 23 Mar 2021 20:17:17
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)	10 Mar 2021 18:50:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Mar 2021 18:50:54
User signature succeeded.	David Diemert (b) (4) (b) (4)	10 Mar 2021 18:40:20
Data point term sent to Coder User entered 'Ibuprofen'	System Hannah Yellin (b) (4) (b) (4)	10 Mar 2021 18:19:25 10 Mar 2021 18:18:16

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:29
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:18:16
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:29
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:26
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.'	(b) (4), (b) (6)	25 Mar 2021 07:39:53
(Site from DM).		
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.'	David Diemert (b) (4)	23 Mar 2021 20:18:19
' answered with 'Updated.' (Site from DM).	(b) (4)	
Signature has been broken.	David Diemert (b) (4)	23 Mar 2021 20:17:17
	(b) (4)	
User entered 'Tooth pain' reason for change: Per Query Resolution	David Diemert (b) (4)	23 Mar 2021 20:17:17
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.'	(b) (4), (b) (6)	22 Mar 2021 06:53:55
(Site from DM).		
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
	(b) (4)	
User entered 'Root canal'	Hannah Yellin (b) (4)	10 Mar 2021 18:18:16
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:29
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '800'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:18:16
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:29
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'mg (mg)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:18:16
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:29
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered empty.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:18:16
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:29
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'once (ONCE)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:18:16

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:29
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered empty.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:18:16
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:29
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Oral (ORAL)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:18:16

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:29
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered empty.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:18:16
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:29
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '09 Mar 2021'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:18:16
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:29
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '0'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:18:16
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:29
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:18:16

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:29
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '09 Mar 2021'	Hannah Yellin (b) (4)	10 Mar 2021 18:18:16

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:29
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:18:16
	(b) (4)	

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:29
User entered empty.	System	10 Mar 2021 18:18:16

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:29
User entered empty.	System	10 Mar 2021 18:18:16

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:29
User entered empty.	System	10 Mar 2021 18:18:16

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Apr 2021 20:20:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Apr 2021 20:20:25
Data point term sent to Coder	System	27 Apr 2021 19:27:59
User entered 'Acetaminophen'	(b) (4), (b) (6)	27 Apr 2021 19:27:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:27:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Sleeve Gastrectomy'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:27:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '975'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:27:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:27:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:27:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'four times daily (QID)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:27:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:27:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:27:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:27:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:08

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:27:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:27:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:27:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:27:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:27:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	27 Apr 2021 19:27:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Apr 2021 19:27:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Apr 2021 19:27:13

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	27 Apr 2021 22:02:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Apr 2021 22:02:08
Data point term sent to Coder	System	27 Apr 2021 19:30:06
User entered 'Ketorolac'	(b) (4), (b) (6)	27 Apr 2021 19:29:21

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:29:21

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Sleeve Gastrectomy'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:29:21

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '15'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:29:21

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:29:21

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:29:21

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:29:21

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Every 6 hours'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:29:21

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:29:21

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:08

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:29:21

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:29:21

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:08

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:29:21

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:29:21

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '23 Apr 2021'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:29:21

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:29:21

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 19:29:21

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 19:29:21

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 19:29:21

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: PROPULSIVES, ATC: PROPULSIVES, PRODUCT: METOCLOPRAMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	28 Apr 2021 00:33:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Apr 2021 00:33:35
Data point term sent to Coder	System	27 Apr 2021 19:32:06
User entered 'Metoclopramide'	(b) (4), (b) (6)	27 Apr 2021 19:31:40

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:31:40

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Sleeve Gastrectomy'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:31:40

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '10'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:31:40

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:31:40

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:31:40

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:31:40

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:08

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'every 6 hours'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:31:40

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:31:40

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:31:40

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:31:40

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:31:40

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:31:40

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '23 Apr 2021'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:31:40

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:31:40

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 19:31:40

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 19:31:40

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 19:31:40

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Apr 2021 21:51:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Apr 2021 21:51:59
Data point term sent to Coder	System	27 Apr 2021 19:35:32
User entered 'Hydromorphone'	(b) (4), (b) (6)	27 Apr 2021 19:34:46

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:34:46

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Sleeve Gastrectomy'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:34:46

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '0.5'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:34:46

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:34:46

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:34:46

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:34:46

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'every 3 hours as needed'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:34:46

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:34:46

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:34:46

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:34:46

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:08

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:34:46

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:34:46

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '23 Apr 2021'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:34:46

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:34:46

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 19:34:46

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 19:34:46

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 19:34:46

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	28 Apr 2021 00:34:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Apr 2021 00:34:02
Data point term sent to Coder	System	27 Apr 2021 19:36:35
User entered 'Ondansetron'	(b) (4), (b) (6)	27 Apr 2021 19:35:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:35:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Sleeve Gastrectomy'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:35:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '4'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:35:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:35:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:35:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:35:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'every 4 hours as needed'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:35:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:35:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:35:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:35:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:35:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:35:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '23 Apr 2021'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:35:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:35:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 19:35:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 19:35:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 19:35:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	28 Apr 2021 00:34:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Apr 2021 00:34:02
Data point term sent to Coder	System	27 Apr 2021 19:37:36
User entered 'Clindamycin'	(b) (4), (b) (6)	27 Apr 2021 19:37:00

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:37:00

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Sleeve Gastrectomy'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:37:00

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '900'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:37:00

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:37:00

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:37:00

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:37:00

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:37:00

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:37:00

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:37:00

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:08

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:37:00

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:37:00

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:37:00

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:37:00

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:37:00

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 19:37:00

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 19:37:00

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 19:37:00

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	28 Apr 2021 00:34:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Apr 2021 00:34:01
Data point term sent to Coder	System	27 Apr 2021 19:38:41
User entered 'Enoxaparin (Lovenox)'	(b) (4), (b) (6)	27 Apr 2021 19:38:35

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:38:35

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Sleeve Gastrectomy'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:38:35

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '40'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:38:35

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:38:35

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:38:35

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:38:35

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:38:35

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:38:35

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:38:35

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:08

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:38:35

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:38:35

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:38:35

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:38:35

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:38:35

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	27 Apr 2021 19:38:35

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Apr 2021 19:38:35

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Apr 2021 19:38:35

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	28 Apr 2021 00:34:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Apr 2021 00:34:36
Data point term sent to Coder	System	27 Apr 2021 19:42:50
User entered 'Oxycodone'	(b) (4), (b) (6)	27 Apr 2021 19:41:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:41:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Sleeve Gastrectomy'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:41:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '5'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:41:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:41:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:41:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:41:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:41:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:41:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:41:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:41:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:41:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:41:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:41:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:41:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 19:41:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 19:41:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 19:41:58

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:08

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: BELLADONNA AND DERIVATIVES, PLAIN, ATC: BELLADONNA ALKALOIDS, TERTIARY AMINES, PRODUCT: HYOSCYAMINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	28 Apr 2021 05:03:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Apr 2021 05:03:14
Data point term sent to Coder	System	27 Apr 2021 19:43:54
User entered 'Hyoscyamine (Levison)'	(b) (4), (b) (6)	27 Apr 2021 19:43:53

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:43:53

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Sleeve Gastrectomy'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:43:53

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '0.125'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:43:53

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:43:53

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:43:53

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:43:53

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:08

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:43:53

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:43:53

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:43:53

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:08

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:43:53

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:43:53

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:43:53

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:43:53

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:43:53

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 19:43:53

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 19:43:53

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 19:43:53

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	28 Apr 2021 00:29:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Apr 2021 00:29:07
Data point term sent to Coder	System	27 Apr 2021 19:46:04
User entered 'Gabapentin'	(b) (4), (b) (6)	27 Apr 2021 19:45:09

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:45:09

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Sleeve Gastrectomy'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:45:09

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '300'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:45:09

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:45:09

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:45:09

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:45:09

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:45:09

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:45:09

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:45:09

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '23 Apr 2021'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:45:09

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:45:09

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:45:09

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:45:09

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:45:09

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	27 Apr 2021 19:45:09

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Apr 2021 19:45:09

US3542030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Apr 2021 19:45:09

US3542030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:12:08

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:47:54
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:10:06
User entered 'Yes (Y)'	(b) (4) David Diemert (b) (4) (b) (4)	18 Nov 2020 21:50:29

US3542030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:12:08

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:31
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:10:06
User entered '23 Sep 2020'	(b) (4) David Diemert (b) (4) (b) (4)	18 Nov 2020 21:51:50

US3542030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:12:08

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:31
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:10:06
User entered 'Tooth crown replacement'	(b) (4) David Diemert (b) (4) (b) (4)	18 Nov 2020 21:51:50

US3542030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:31
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:10:06
User entered 'Adverse Event (AE)'	(b) (4) David Diemert (b) (4) (b) (4)	18 Nov 2020 21:51:50

US3542030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:12:08

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:31
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:10:06
User entered empty.	(b) (4) David Diemert (b) (4)	18 Nov 2020 21:51:50

US3542030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:12:08

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:34
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:57:30
User entered '28 Sep 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:17:33

US3542030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:12:08

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:34
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:57:30
User entered 'Dental filling replacement'	(b) (4) Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:17:33

US3542030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:34
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:57:30
User entered 'Medical History (MH)'	(b) (4) Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:17:33

US3542030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:12:08

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:34
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:57:30
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:17:33

US3542030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:12:08

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:39
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:57:30
User entered '19 Oct 2020'	(b) (4) Erika Faust (b) (4)	18 Dec 2020 16:17:54

US3542030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:12:08

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:39
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:57:30
User entered 'Tooth crown repair'	(b) (4) Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:17:54

US3542030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:39
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:57:30
User entered 'Adverse Event (AE)'	(b) (4) Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:17:54

US3542030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:12:08

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:39
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:57:30
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:17:54

US3542030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:12:08

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:42
User signature succeeded.	David Diemert (b) (4)	23 Feb 2021 16:39:46
User entered '17 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	19 Feb 2021 17:40:49

US3542030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:12:08

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:42
User signature succeeded.	David Diemert (b) (4)	23 Feb 2021 16:39:46
User entered 'Upper Endoscopy'	(b) (4) Erika Faust (b) (4) (b) (4)	19 Feb 2021 17:40:49

US3542030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:42
User closed query 'Per DM CLR: Indication = OTHER, however, please confirm if the indication could be recorded as one of the available choice (i.e. Diagnostic). Reconcile and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 05:18:03
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:57
Query 'Per DM CLR: Indication = OTHER, however, please confirm if the indication could be recorded as one of the available choice (i.e. Diagnostic). Reconcile and update as appropriate, otherwise clarify. ' answered with 'Updated.' (Site from DM).	David Diemert (b) (4)	03 Mar 2021 20:35:28
Signature has been broken.	David Diemert (b) (4)	03 Mar 2021 20:34:27
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Per Query Resolution	David Diemert (b) (4)	03 Mar 2021 20:34:27
User opened query 'Per DM CLR: Indication = OTHER, however, please confirm if the indication could be recorded as one of the available choice (i.e. Diagnostic). Reconcile and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 06:58:37
User signature succeeded.	David Diemert (b) (4)	23 Feb 2021 16:39:46
User entered 'Other (OTHER)'	Erika Faust (b) (4)	19 Feb 2021 17:40:49

US3542030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:12:08

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:42
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:57
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	03 Mar 2021 20:34:27
	(b) (4)	
User entered empty; reason for change Per Query Resolution	David Diemert (b) (4)	03 Mar 2021 20:34:27
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	23 Feb 2021 16:39:46
	(b) (4)	
User entered 'Medical Clearance for Bariatric Surgery'	Erika Faust (b) (4)	19 Feb 2021 17:40:49
	(b) (4)	

US3542030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:12:08

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:49
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered '09 Mar 2021'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:15:44
	(b) (4)	

US3542030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:12:08

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:49
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Root canal'	(b) (4) Hannah Yellin (b) (4) (b) (4)	10 Mar 2021 18:15:44

US3542030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:49
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered 'Medical History (MH)'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:15:44
	(b) (4)	

US3542030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:12:08

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:44:49
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:20
User entered empty.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 18:15:44
	(b) (4)	

US3542030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:12:08

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:54:22

US3542030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:12:08

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Sleeve Gastrectomy'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:54:22

US3542030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:54:22

US3542030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:12:08

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'SAE (Morbid Obesity)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:54:22

US3542030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:12:08

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 20:04:02

US3542030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:12:08

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Hiatal hernia repair'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 20:04:02

US3542030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:12:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 20:04:02

US3542030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:12:08

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'SAE (Hiatal hernia)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 20:04:02

US3542030

Folder: SAE USA-US084-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:08

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:17:13
User entered 'USA-US084-2021-MRNA-1273-P301000011'	System	27 Apr 2021 18:14:28

US3542030

Folder: SAE USA-US084-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:08

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:17:25
User entered 'Yes (Y)'	System	27 Apr 2021 18:14:28

US3542030

Folder: SAE USA-US084-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:08

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:17:25
User entered 'No (N)'	System	27 Apr 2021 18:14:28

US3542030

Folder: SAE USA-US084-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:17:25
User entered 'No (N)'	System	27 Apr 2021 18:14:28

US3542030

Folder: SAE USA-US084-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:17:25
User entered 'Yes (Y)'	System	27 Apr 2021 18:14:28

US3542030

Folder: SAE USA-US084-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:17:25
User entered 'No (N)'	System	27 Apr 2021 18:14:28

US3542030

Folder: SAE USA-US084-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:17:25
User entered 'No (N)'	System	27 Apr 2021 18:14:28

US3542030

Folder: SAE USA-US084-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:17:25
User entered 'No (N)'	System	27 Apr 2021 18:14:28

US3542030

Folder: SAE USA-US084-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:17:25
User entered 'David'	System	27 Apr 2021 18:14:28

US3542030

Folder: SAE USA-US084-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:17:25
User entered 'Diemert'	System	27 Apr 2021 18:14:28

US3542030

Folder: SAE USA-US084-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:08

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:17:25
User entered '2300 Eye Street NW'	System	27 Apr 2021 18:14:28

US3542030

Folder: SAE USA-US084-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:08

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:17:25
User entered 'Washington'	System	27 Apr 2021 18:14:28

US3542030

Folder: SAE USA-US084-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:08

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:17:25
User entered '20037'	System	27 Apr 2021 18:14:28

US3542030

Folder: SAE USA-US084-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:08

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'US'	(b) (4) System	27 Apr 2021 18:17:36

US3542030

Folder: SAE USA-US084-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Apr 2021 18:17:36

US3542030

Folder: SAE USA-US084-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:08

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:17:13
User entered 'USA-US084-2021-MRNA-1273-P301000011'	System	27 Apr 2021 18:14:28

US3542030

Folder: SAE USA-US084-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:08

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:17:25
User entered 'Yes (Y)'	System	27 Apr 2021 18:14:28

US3542030

Folder: SAE USA-US084-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:08

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:17:25
User entered 'No (N)'	System	27 Apr 2021 18:14:28

US3542030

Folder: SAE USA-US084-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:17:25
User entered 'No (N)'	System	27 Apr 2021 18:14:28

US3542030

Folder: SAE USA-US084-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:17:25
User entered 'Yes (Y)'	System	27 Apr 2021 18:14:28

US3542030

Folder: SAE USA-US084-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:17:25
User entered 'No (N)'	System	27 Apr 2021 18:14:28

US3542030

Folder: SAE USA-US084-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:17:25
User entered 'No (N)'	System	27 Apr 2021 18:14:28

US3542030

Folder: SAE USA-US084-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:17:25
User entered 'No (N)'	System	27 Apr 2021 18:14:28

US3542030

Folder: SAE USA-US084-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:17:25
User entered 'David'	System	27 Apr 2021 18:14:28

US3542030

Folder: SAE USA-US084-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:17:25
User entered 'Diemert'	System	27 Apr 2021 18:14:28

US3542030

Folder: SAE USA-US084-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:08

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:17:25
User entered '2300 Eye Street NW'	System	27 Apr 2021 18:14:28

US3542030

Folder: SAE USA-US084-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:08

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:17:25
User entered 'Washington'	System	27 Apr 2021 18:14:28

US3542030

Folder: SAE USA-US084-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:08

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:17:25
User entered '20037'	System	27 Apr 2021 18:14:28

US3542030

Folder: SAE USA-US084-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:08

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'US'	(b) (4) System	27 Apr 2021 18:17:36

US3542030

Folder: SAE USA-US084-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Apr 2021 18:17:36

US3542030

Folder: SAE USA-US084-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:12:08

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered '27/Apr/2021 14:17'	(b) (4) System	27 Apr 2021 18:17:36

US3542030

Folder: SAE USA-US084-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:12:08

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	28 Apr 2021 22:00:17
User entered 'I'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:17:36