

US3512217 (Prod: Jacksonville Center for Clinical Research Center)

Generated By: KC Joubran

Generated On: 10 Jun 2021 07:55:38

All time stamps listed in this document are displayed in GMT

US3512217

Form: Participant Creation

Data signed: (b) (4) 12 Feb 2021 21:53:28

Generated On: 10 Jun 2021 07:55:38

[Participant ID](#)

US3512217

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

US3512217

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

Date of Birth (MMM yyyy)	(b) (6) 1956
Age	64
Age Units	YEARS
Age (Derived)	64
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 21:53:29

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 05 Mar 2021 22:43:41

Generated On: 10 Jun 2021 07:55:38

Condition	ACID REFLUX
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 05 Mar 2021 22:43:41

Generated On: 10 Jun 2021 07:55:38

Condition	HEPATITIS C
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 05 Mar 2021 22:43:41

Generated On: 10 Jun 2021 07:55:38

Condition	BENIGN PROSTATIC HYPERPLASIA
Start date (dd MMM yyyy)	UN JUL 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 05 Mar 2021 22:43:41

Generated On: 10 Jun 2021 07:55:38

Condition	NEARSIGHTED
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 05 Mar 2021 22:43:41

Generated On: 10 Jun 2021 07:55:38

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 05 Mar 2021 22:43:41

Generated On: 10 Jun 2021 07:55:38

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 05 Mar 2021 22:43:41

Generated On: 10 Jun 2021 07:55:38

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 05 Mar 2021 22:43:41

Generated On: 10 Jun 2021 07:55:38

Condition	BROKEN LEFT ARM
Start date (dd MMM yyyy)	UN UNK 1985
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1985
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	JAN 1985
Stop Year (derived)	1985

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 05 Mar 2021 22:43:41

Generated On: 10 Jun 2021 07:55:38

Condition	TITANIUM SCREW INSERTED LEFT ARM
Start date (dd MMM yyyy)	UN UNK 1985
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1985
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	JAN 1985
Stop Year (derived)	1985

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 05 Mar 2021 22:43:41

Generated On: 10 Jun 2021 07:55:38

Condition	BILATERAL LOWER LEG SWELLING
Start date (dd MMM yyyy)	UN JUL 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 05 Mar 2021 22:43:41

Generated On: 10 Jun 2021 07:55:38

Condition	MYOCARDIAL INFARCTION
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 05 Mar 2021 22:43:41

Generated On: 10 Jun 2021 07:55:38

Condition	PORPHYRIA CUTANAE TARDA
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 05 Mar 2021 22:43:41

Generated On: 10 Jun 2021 07:55:38

Condition	MODERATE AORTIC VALVE STENOSIS
Start date (dd MMM yyyy)	24 JUL 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 05 Mar 2021 22:43:41

Generated On: 10 Jun 2021 07:55:38

Condition	CONGENITAL AORTIC VALVE INSUFFICIENCY
Start date (dd MMM yyyy)	(b) (6) 1956
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	(b) (6) 1956
Start Year (derived)	1956
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	4 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:30 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 10:30
Height (<i>xxx.x</i>)	66 in
Weight (<i>xxx.x</i>)	174.6 lb
BMI (<i>xxx.x</i>)	28.24010 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 21:53:29

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	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	True
Specify	PLANS ON ROUTINELY GOING TO PLACES WHERE PEOPLE GATHER (GROCERY, RESTAURANTS); INTERACTS W/>5 PEOPLE OUTSIDE OF WORK AND HOME

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

What was the date of randomization? (dd MMM yyyy) 04 SEP 2020

What was the participant's randomization number? 111543

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) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

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) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 SEP 2020
Time of assessment (00:00-23:59)	10:30 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 10:30
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 SEP 2020
Time of assessment (00:00-23:59)	11:59 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 11:59
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

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) 4 SEP 2020

What was the treatment time? (00:00-23:59) 11:28 (24 HR)

Treatment Date and Time (derived) 4 SEP 2020 11:28

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) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

4 SEP 2020

Collection time (00:00-23:59)

11:06 (24 HR)

Collection date and time (derived)

4 SEP 2020 11:06

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

Collection date (dd MMM yyyy)			4 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:00	4 SEP 2020 11:00
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 12:00

PC Open Date & Time

04 SEP 2020 11:48

PC Close Date & Time

04 SEP 2020 14:18

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.1 °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	04 SEP 2020 21:54
PC Open Date & Time	04 SEP 2020 15:13
PC Close Date & Time	05 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:55:38

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 19:04

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:55:38

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 18:08

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:55:38

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

97.6 °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

07 SEP 2020 21:31

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

08 SEP 2020 22:56

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:55:38

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

98.5 °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

09 SEP 2020 18:02

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 18:40

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

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

04 SEP 2020 12:04

PC Open Date & Time

04 SEP 2020 11:48

PC Close Date & Time

04 SEP 2020 14:18

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

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

04 SEP 2020 21:55

PC Open Date & Time

04 SEP 2020 15:13

PC Close Date & Time

05 SEP 2020 11:59

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:55:38

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

05 SEP 2020 19:06

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:55:38

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

06 SEP 2020 18:10

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:55:38

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

07 SEP 2020 21:32

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:55:38

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

08 SEP 2020 22:56

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:55:38

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

09 SEP 2020 18:03

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:55:38

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

10 SEP 2020 18:40

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 12:03
PC Open Date & Time	04 SEP 2020 11:48
PC Close Date & Time	04 SEP 2020 14:18

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 21:56
PC Open Date & Time	04 SEP 2020 15:13
PC Close Date & Time	05 SEP 2020 11:59

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:55:38

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 ☒

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:55:38

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 19:06
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:55:38

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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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:55:38

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 18:11
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:55:38

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 2241

EAB) (1725)

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:55:38

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 21:32
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:55:38

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

61 of 2241

EAB) (1725)

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:55:38

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 22:57
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:55:38

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 ☒

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:55:38

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 18:04
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:55:38

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 ☒

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:55:38

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 18:41
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3512217

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512217

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512217

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:53:28

Generated On: 10 Jun 2021 07:55:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512217

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:53:28

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512217

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:53:28

Generated On: 10 Jun 2021 07:55:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512217

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:53:28

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512217

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3512217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 OCT 2020
Time of assessment (00:00-23:59)	11:12 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 11:12
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3512217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	2 OCT 2020
Time of assessment (00:00-23:59)	12:40 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 12:40
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3512217

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 OCT 2020

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

US3512217

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

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) 2 OCT 2020

What was the treatment time? (00:00-23:59) 12:08 (24 HR)

Treatment Date and Time (derived) 2 OCT 2020 12:08

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

What was the frequency of the study treatment dosing? ONCE

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

US3512217

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

2 OCT 2020

Collection time (00:00-23:59)

11:27 (24 HR)

Collection date and time (derived)

2 OCT 2020 11:27

US3512217

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

Collection date (dd MMM yyyy)			2 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:20	2 OCT 2020 11:20
Nasopharyngeal Swab 2	No		

US3512217

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

02 OCT 2020 12:42

PC Open Date & Time

02 OCT 2020 12:28

PC Close Date & Time

02 OCT 2020 14:58

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.7 °F

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

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

PC Time Stamp	02 OCT 2020 18:31
PC Open Date & Time	02 OCT 2020 15:53
PC Close Date & Time	03 OCT 2020 11:59

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:55:38

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 19:53

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:55:38

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

98.7 °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

04 OCT 2020 20:27

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:55:38

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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 23:29

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

06 OCT 2020 19:51

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:55:38

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

98.4 °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

07 OCT 2020 19:31

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

08 OCT 2020 22:32

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 12:43

PC Open Date & Time

02 OCT 2020 12:28

PC Close Date & Time

02 OCT 2020 14:58

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

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

02 OCT 2020 18:32

PC Open Date & Time

02 OCT 2020 15:53

PC Close Date & Time

03 OCT 2020 11:59

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:55:38

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

03 OCT 2020 19:53

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:55:38

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

04 OCT 2020 20:28

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:55:38

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

05 OCT 2020 23:29

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:55:38

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

06 OCT 2020 19:51

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:55:38

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

07 OCT 2020 19:32

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:55:38

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

08 OCT 2020 22:32

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 12:44
PC Open Date & Time	02 OCT 2020 12:28
PC Close Date & Time	02 OCT 2020 14:58

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 18:32
PC Open Date & Time	02 OCT 2020 15:53
PC Close Date & Time	03 OCT 2020 11:59

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:55:38

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 ☒

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:55:38

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 19:54
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:55:38

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 ☒

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:55:38

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 20:28
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:55:38

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 23:30
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:55:38

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 ☒

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:55:38

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 19:52
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:55:38

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 ☒

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:55:38

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 19:32
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:55:38

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 ☒

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:55:38

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 22:33
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3512217

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:53:28

Generated On: 10 Jun 2021 07:55:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512217

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:53:28

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512217

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512217

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:53:28

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512217

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512217

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512217

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3512217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	30 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	10:30 (24 HR)
Vital Signs Date and Time (derived)	30 OCT 2020 10:30
Temperature (<i>xxx.x</i>)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	70 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	64 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3512217

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

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.

US3512217

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 OCT 2020
Collection time (00:00-23:59)	10:39 (24 HR)
Collection date and time (derived)	30 OCT 2020 10:39

US3512217

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 NOV 2020 17:13:48

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

14 NOV 2020 00:21:05

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission	
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 DEC 2020 16:56:13

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 DEC 2020 14:44:47
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

13 DEC 2020 14:10:41

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

21 DEC 2020 09:50:27

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

28 DEC 2020 23:15:13

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	03 JAN 2021 23:06:06
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

11 JAN 2021 18:05:39

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

21 JAN 2021 16:11:07

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

28 JAN 2021 19:18:04

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

01 FEB 2021 07:09:38

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

07 FEB 2021 20:01:17

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

15 FEB 2021 08:37:33

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

22 FEB 2021 08:56:45

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

01 MAR 2021 09:45:33

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 09:53:41

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 MAR 2021 14:08:06
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 12:52:04

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

29 MAR 2021 08:40:38

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

07 APR 2021 10:55:54

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

12 APR 2021 06:51:21

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 20:24:27

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

26 APR 2021 22:42:22

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

02 MAY 2021 14:41:56

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 250

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

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

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

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

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

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

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

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

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 JUN 2021 00:01
Patient Cloud Close Date & Time	10 JUN 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 JUN 2021 00:01
Patient Cloud Close Date & Time	17 JUN 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 JUN 2021 00:01
Patient Cloud Close Date & Time	01 JUL 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 JUL 2021 00:01
Patient Cloud Close Date & Time	08 JUL 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 JUL 2021 00:01
Patient Cloud Close Date & Time	15 JUL 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 JUL 2021 00:01
Patient Cloud Close Date & Time	22 JUL 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Patient Cloud Open Date & Time	15 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 AUG 2021 00:01
Patient Cloud Close Date & Time	26 AUG 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 SEP 2021 00:01
Patient Cloud Close Date & Time	30 SEP 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

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

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 OCT 2021 00:01
Patient Cloud Close Date & Time	21 OCT 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	31 OCT 2021 00:01
Patient Cloud Close Date & Time	04 NOV 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 NOV 2021 00:01
Patient Cloud Close Date & Time	11 NOV 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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°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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 MAR 2022 00:01
Patient Cloud Close Date & Time	17 MAR 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 APR 2022 00:01
Patient Cloud Close Date & Time	14 APR 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission	
Patient Cloud Open Date & Time	17 APR 2022 00:01
Patient Cloud Close Date & Time	21 APR 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 JUN 2022 00:01
Patient Cloud Close Date & Time	30 JUN 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUL 2022 00:01
Patient Cloud Close Date & Time	14 JUL 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Patient Cloud Open Date & Time	21 AUG 2022 00:01
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Patient Cloud Close Date & Time	25 AUG 2022 23:59
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US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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°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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 733

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

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

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

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

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

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

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

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

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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°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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 SEP 2022 00:01
Patient Cloud Close Date & Time	29 SEP 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2022 00:01
Patient Cloud Close Date & Time	20 OCT 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Patient Cloud Open Date & Time	23 OCT 2022 00:01
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Patient Cloud Close Date & Time	27 OCT 2022 23:59
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US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3512217

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 07:55:38

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 09:45:18

US3512217

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512217

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:53:29

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512217

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:53:28

Generated On: 10 Jun 2021 07:55:38

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3512217

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:53:28

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512217

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:53:28

Generated On: 10 Jun 2021 07:55:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512217

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:26:20

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512217

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 20:02:01

Generated On: 10 Jun 2021 07:55:38

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3512217

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 20:02:01

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512217

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 19:29:55

Generated On: 10 Jun 2021 07:55:38

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

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

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

Folder OID	VISIT4
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US3512217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 19:29:55

Generated On: 10 Jun 2021 07:55:38

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) _____

US3512217

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 19:29:55

Generated On: 10 Jun 2021 07:55:38

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.

US3512217

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 19:29:55

Generated On: 10 Jun 2021 07:55:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	02 APR 2021
Collection time (00:00-23:59)	10:54 (24 HR)
Collection date and time (derived)	02 APR 2021 10:54

US3512217

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 12:06:10

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512217

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 03 May 2021 15:13:58

Generated On: 10 Jun 2021 07:55:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512217

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 03 May 2021 15:13:58

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512217

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

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

US3512217

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3512217

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 07:55:38

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

US3512217

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 07:55:38

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3512217

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

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:53:28

Generated On: 10 Jun 2021 07:55:38

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

Visit date (dd MMM yyyy)	29 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3512217

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

Form: Unblinding

Data signed: (b) (4) 15 Mar 2021 12:51:20

Generated On: 10 Jun 2021 07:55:38

Date of updated informed consent (dd MMM yyyy) 29 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 (dd MMM yyyy) 29 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 _____
Continuing with mRNA-1273 _____

US3512217

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:53:28

Generated On: 10 Jun 2021 07:55:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 JAN 2021

Collection time (00:00-23:59)

10:34 (24 HR)

Collection date and time (derived)

29 JAN 2021 10:34

US3512217

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Feb 2021 21:53:28

Generated On: 10 Jun 2021 07:55:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 JAN 2021
Collection time (00:00 - 23:59)	10:30
Collection Date and Time (derived)	29 JAN 2021 10:30

US3512217

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Feb 2021 21:53:28

Generated On: 10 Jun 2021 07:55:38

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3512217

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 12:05:59

Generated On: 10 Jun 2021 07:55:38

AEID

Adverse event

LOW BACK 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)

16 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)

26 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 (1)

Data signed: (b) (4) 08 Apr 2021 12:05:59

Generated On: 10 Jun 2021 07:55:38

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

US3512217

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 12:05:59

Generated On: 10 Jun 2021 07:55:38

AEID	USA-US065-2021-MRNA-1273-P30 1000001
Adverse event	SYNCPAL EPISODE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	31 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	31 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	31 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	02 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 12:05:59

Generated On: 10 Jun 2021 07:55:38

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 <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT REPORTED HOSPITALIZATION ON 31DEC2020 DUE TO SYNCOPAL EPISODE. UNDERLYING CAUSE UNKNOWN PER MEDICAL RECORDS.
Serious Adverse Event Derived (CSA Programming Field Only)	1

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 12:05:59

Generated On: 10 Jun 2021 07:55:38

Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3512217

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 08 Apr 2021 12:05:59

Generated On: 10 Jun 2021 07:55:38

AEID	
Adverse event	NECK INJURY
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	31 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	4 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 08 Apr 2021 12:05:59

Generated On: 10 Jun 2021 07:55:38

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

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 08 Apr 2021 12:05:59

Generated On: 10 Jun 2021 07:55:38

AEID	
Adverse event	RIGHT SHOULDER INJURY
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	31 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	4 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 08 Apr 2021 12:05:59

Generated On: 10 Jun 2021 07:55:38

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

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Feb 2021 21:53:28

Generated On: 10 Jun 2021 07:55:38

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

Yes ☒

No ☐

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

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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

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

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US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2009	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

Name of Medication FUROSEMIDES

Prophylaxis Yes ☐
No ☒

Indication BILATERAL LOWER LEG
SWELLING

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

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN JUL 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	18 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

Name of Medication FINASTERIDE

Prophylaxis Yes ☐
No ☒

Indication BENIGN PROSTATIC
HYPERPLASIA

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN JUL 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	18 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

Name of Medication NIFEDIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 90

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2009	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	4 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

Name of Medication ADVIL LIQUID

Prophylaxis Yes ☐
No ☒

Indication LOW BACK PAIN

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) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

Name of Medication BUPROPION XL

Prophylaxis Yes ☐
No ☒

Indication SMOKING CESSATION

Dose per administration 150

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) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	7 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication SEASONAL FLU PROPHYLAXIS

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 (8)

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		4 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 4 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

Name of Medication	HEPARIN SODIUM
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	DVT PROPHYLAXIS
Dose per administration	5000
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	UNITS
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input checked="" type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	1 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 1 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication SYNCOPAL EPISODE

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 (10)

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		31 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		31 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

Name of Medication HYDROCODONE BITARTRATE
ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication NECK AND RIGHT SHOULDER
INJURY

Dose per administration 1

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

If dose unit is Other, specify UNIT

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 (11)

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		31 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		31 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

Name of Medication HEPARIN SODIUM

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS DEEP VEIN
THROMBOSIS

Dose per administration 5000

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

If dose unit is Other, specify UNIT/ML

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 (12)

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		1 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		1 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

Name of Medication ERGOCALCIFEROL

Prophylaxis Yes ☒
No ☐

Indication LOW VITAMIN D PROPHYLAXIS

Dose per administration 50000

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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US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	18 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input checked="" type="radio"/>
	804	<input type="radio"/>

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

Name of Medication CHANTIX

Prophylaxis Yes ☐
No ☒

Indication SMOKING CESSATION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	25 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

Name of Medication CHANTIX

Prophylaxis Yes ☐
No ☒

Indication SMOKING CESSATION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3512217

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 21:26:20

Generated On: 10 Jun 2021 07:55:38

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3512217

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

SAEID	USA-US065-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	KOREN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

SAEID	USA-US065-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	KOREN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	06/JAN/2021 11:25
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

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

SAEID	USA-US065-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	KOREN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	10/FEB/2021 11:23
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

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

SAEID	USA-US065-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	KOREN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	17/FEB/2021 09:49
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

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

SAEID	USA-US065-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	KOREN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	08/MAR/2021 11:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

SAEID	USA-US065-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	KOREN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	17/MAR/2021 07:45
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

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 08 Apr 2021 12:06:09

Generated On: 10 Jun 2021 07:55:38

SAEID	USA-US065-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	KOREN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	06/APR/2021 14:11
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

US3512217 (Prod: Jacksonville Center for Clinical Research Center)

US3512217

Form: Participant Creation

Generated On: 10 Jun 2021 07:55:38

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:33
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'US3512217'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 14:39:50

US3512217

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:42:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	04 Sep 2020 15:37:00
	(b) (4)	

US3512217

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	06 Oct 2020 16:42:59
User entered '04 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 14:39:51

US3512217

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[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 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	06 Oct 2020 16:42:59
User entered 'Clinic (Clinic)'	Allison Crain (b) (4)	04 Sep 2020 15:37:00

US3512217

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered 'SCRN'	System	04 Sep 2020 15:37:00

US3512217

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:55:38

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	06 Oct 2020 16:46:22
User entered (b) (6) 1956'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 14:39:52

US3512217

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:55:38

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:46:22
User entered '64'	Allison Crain (b) (4)	04 Sep 2020 15:37:18
	(b) (4)	

US3512217

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:55:38

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered 'YEARS'	System	04 Sep 2020 15:37:18

US3512217

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:55:38

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered '64'	System	04 Sep 2020 15:37:29

US3512217

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:55:38

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:46:22
User entered 'Male (M)'	Allison Crain (b) (4)	04 Sep 2020 15:37:18
	(b) (4)	

US3512217

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:55:38

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:46:22
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Allison Crain (b) (4) (b) (4)	04 Sep 2020 15:37:18

US3512217

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:55:38

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:46:22
User entered 'I'	Allison Crain (b) (4)	04 Sep 2020 15:37:18
	(b) (4)	

US3512217

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:55:38

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:46:22
User entered '0'	Allison Crain (b) (4)	04 Sep 2020 15:37:18
	(b) (4)	

US3512217

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:55:38

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:46:22
User entered '0'	Allison Crain (b) (4)	04 Sep 2020 15:37:18
	(b) (4)	

US3512217

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:55:38

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:46:22
User entered '0'	Allison Crain (b) (4)	04 Sep 2020 15:37:18

US3512217

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:55:38

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:46:22
User entered '0'	Allison Crain (b) (4)	04 Sep 2020 15:37:18
	(b) (4)	

US3512217

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:55:38

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:46:22
User entered '0'	Allison Crain (b) (4)	04 Sep 2020 15:37:18
	(b) (4)	

US3512217

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:55:38

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:46:22
User entered empty.	Allison Crain (b) (4)	04 Sep 2020 15:37:18
	(b) (4)	

US3512217

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:55:38

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	06 Oct 2020 16:46:22
User entered '0'	Allison Crain (b) (4)	04 Sep 2020 15:37:18

US3512217

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:55:38

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:46:22
User entered '0'	Allison Crain (b) (4)	04 Sep 2020 15:37:18
	(b) (4)	

US3512217

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:55:38

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:46:30
User entered '4 Sep 2020'	Allison Crain (b) (4)	04 Sep 2020 15:37:29
	(b) (4)	

US3512217

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered 'Sep 2020'	System	04 Sep 2020 15:37:29

US3512217

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered '2020'	System	04 Sep 2020 15:37:29

US3512217

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:55:38

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:46:30
User entered 'Amendment 3 (3)'	Allison Crain (b) (4)	04 Sep 2020 15:37:29

US3512217

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:46:30
User entered 'Yes (Y)'	Allison Crain (b) (4)	04 Sep 2020 15:37:29
	(b) (4)	

US3512217

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	06 Oct 2020 16:46:30
User entered empty.	Allison Crain (b) (4)	04 Sep 2020 15:37:29

US3512217

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:55:38

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:46:30
User entered empty.	Allison Crain (b) (4)	04 Sep 2020 15:37:29

US3512217

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:55:38

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:46:30
User entered 'No (N)'	Allison Crain (b) (4)	04 Sep 2020 15:37:29
	(b) (4)	

US3512217

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:55:38

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	06 Oct 2020 16:46:30
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 14:39:51

US3512217

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:55:38

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered 'I'	System	04 Sep 2020 15:37:33

US3512217

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	06 Oct 2020 16:47:16
User entered 'Yes (Y)'	Allison Crain (b) (4)	04 Sep 2020 15:37:33

US3512217

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 07:55:38

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:47:26
User entered 'Yes (Y)'	Allison Crain (b) (4)	04 Sep 2020 15:49:57
	(b) (4)	

US3512217

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:55:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
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: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 18:11:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 18:11:46
Data point term sent to Coder	System	04 Sep 2020 18:10:24
User entered 'acid reflux'	Taylor Johnson (b) (4)	04 Sep 2020 18:10:05

US3512217

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'un UNK 1990'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:10:05

US3512217

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered '0'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:10:05

US3512217

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:55:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:10:05

US3512217

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered empty.	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:10:05

US3512217

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:55:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered '0'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:10:05

US3512217

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered 'Jan 1990'	System	04 Sep 2020 18:10:05

US3512217

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered '1990'	System	04 Sep 2020 18:10:05

US3512217

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered empty.	System	04 Sep 2020 18:10:05

US3512217

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered empty.	System	04 Sep 2020 18:10:05

US3512217

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:55:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Hepatitis viral infections, PT: Hepatitis C, LLT: Hepatitis C - version MedDRA\\23.0.	(b) (4)	
	Coder Import (b) (4)	04 Sep 2020 18:12:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	
	Coder Import (b) (4)	04 Sep 2020 18:12:49
Data point term sent to Coder	System	04 Sep 2020 18:11:41
User entered 'hepatitis c'	Taylor Johnson (b) (4)	04 Sep 2020 18:10:40
	(b) (4)	

US3512217

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'un UNK 2014'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:10:40

US3512217

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered '0'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:10:40

US3512217

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:55:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:10:40

US3512217

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'un UNK 2016'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:10:40

US3512217

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:55:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered '0'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:10:40

US3512217

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered 'Jan 2014'	System	04 Sep 2020 18:10:40

US3512217

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered '2014'	System	04 Sep 2020 18:10:40

US3512217

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered 'Jan 2016'	System	04 Sep 2020 18:10:40

US3512217

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered '2016'	System	04 Sep 2020 18:10:40

US3512217

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:55:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4)	02 Mar 2021 11:58:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Mar 2021 11:58:42
Data point term sent to Coder	System	02 Mar 2021 11:57:52
Coding entries removed.	Allison Crain (b) (4)	02 Mar 2021 11:57:45
Signature has been broken.	(b) (4)	
	Allison Crain (b) (4)	02 Mar 2021 11:57:45
User entered 'BENIGN PROSTATIC HYPERPLASIA' reason for change: Data Entry Error	(b) (4)	
	Allison Crain (b) (4)	02 Mar 2021 11:57:45
User signature succeeded.	(b) (4)	
	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urine flow decreased, LLT: Urine flow decreased - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 11:54:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 11:54:54
Data point term sent to Coder	System	04 Sep 2020 18:12:42
User entered 'urination problems decreased flow'	Taylor Johnson (b) (4)	04 Sep 2020 18:11:48
	(b) (4)	

US3512217

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'un Jul 2020'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:11:48

US3512217

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered '0'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:11:48

US3512217

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:55:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:11:48

US3512217

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered empty.	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:11:48

US3512217

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:55:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered '0'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:11:48

US3512217

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered 'Jul 2020'	System	04 Sep 2020 18:11:48

US3512217

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered '2020'	System	04 Sep 2020 18:11:48

US3512217

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered empty.	System	04 Sep 2020 18:11:48

US3512217

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered empty.	System	04 Sep 2020 18:11:48

US3512217

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:55:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Nearsighted - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 18:13:40
Data point term sent to Coder	(b) (4)	
User entered 'nearsighted'	System	04 Sep 2020 18:12:43
	Taylor Johnson (b) (4)	04 Sep 2020 18:12:02
	(b) (4)	

US3512217

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'un UNK 2013'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:12:02

US3512217

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered '0'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:12:02

US3512217

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:55:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:12:02

US3512217

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered empty.	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:12:02

US3512217

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:55:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered '0'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:12:02

US3512217

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered 'Jan 2013'	System	04 Sep 2020 18:12:02

US3512217

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered '2013'	System	04 Sep 2020 18:12:02

US3512217

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered empty.	System	04 Sep 2020 18:12:02

US3512217

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered empty.	System	04 Sep 2020 18:12:02

US3512217

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:55:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	04 Sep 2020 18:13:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:13:39
Data point term sent to Coder	System	04 Sep 2020 18:12:43
User entered 'hypercholesterolemia'	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:12:37

US3512217

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'un UNK 2010'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:12:37

US3512217

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered '0'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:12:37

US3512217

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:55:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:12:37

US3512217

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered empty.	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:12:37

US3512217

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:55:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered '0'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:12:37

US3512217

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered 'Jan 2010'	System	04 Sep 2020 18:12:37

US3512217

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered '2010'	System	04 Sep 2020 18:12:37

US3512217

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered empty.	System	04 Sep 2020 18:12:37

US3512217

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered empty.	System	04 Sep 2020 18:12:37

US3512217

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:55:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User coded data point as SOC: Vascular disorders, HLTG: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 18:14:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 18:14:45
Data point term sent to Coder	System	04 Sep 2020 18:13:48
User entered 'hypertension'	Taylor Johnson (b) (4)	04 Sep 2020 18:13:05

US3512217

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'un UNK 2009'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:13:05

US3512217

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered '0'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:13:05

US3512217

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:55:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:13:05

US3512217

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered empty.	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:13:05

US3512217

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:55:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered '0'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:13:05

US3512217

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered 'Jan 2009'	System	04 Sep 2020 18:13:05

US3512217

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered '2009'	System	04 Sep 2020 18:13:05

US3512217

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered empty.	System	04 Sep 2020 18:13:05

US3512217

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered empty.	System	04 Sep 2020 18:13:05

US3512217

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:55:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	04 Sep 2020 18:19:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:19:39
Data point term sent to Coder	System	04 Sep 2020 18:19:08
User entered 'coronary artery disease'	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:18:19

US3512217

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'un UNK 2008'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:18:19

US3512217

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered '0'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:18:19

US3512217

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:55:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:18:19

US3512217

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered empty.	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:18:19

US3512217

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:55:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered '0'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:18:19

US3512217

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered 'Jan 2008'	System	04 Sep 2020 18:18:19

US3512217

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered '2008'	System	04 Sep 2020 18:18:19

US3512217

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered empty.	System	04 Sep 2020 18:18:19

US3512217

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered empty.	System	04 Sep 2020 18:18:19

US3512217

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:55:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Upper limb fracture, LLT: Arm fracture - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	04 Sep 2020 18:21:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:21:46
Data point term sent to Coder	System	04 Sep 2020 18:21:15
User entered 'broken left arm'	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:20:27

US3512217

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'un UNK 1985'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:20:27

US3512217

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered '0'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:20:27

US3512217

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:55:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:20:27

US3512217

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'un UNK 1985'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:20:27

US3512217

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:55:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered '0'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:20:27

US3512217

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered 'Jan 1985'	System	04 Sep 2020 18:20:27

US3512217

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered '1985'	System	04 Sep 2020 18:20:27

US3512217

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered 'Jan 1985'	System	04 Sep 2020 18:20:27

US3512217

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered '1985'	System	04 Sep 2020 18:20:27

US3512217

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:55:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Medical device implantation, LLT: Insertion of surgical hardware - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 09:08:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 09:08:51
Data point term sent to Coder	System	04 Sep 2020 18:22:21
User entered 'titanium screw inserted left arm'	Taylor Johnson (b) (4)	04 Sep 2020 18:22:02

US3512217

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'un UNK 1985'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:22:02

US3512217

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered '0'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:22:02

US3512217

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:55:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:22:02

US3512217

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'un UNK 1985'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:22:02

US3512217

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:55:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered '0'	(b) (4) Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:22:02

US3512217

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered 'Jan 1985'	System	04 Sep 2020 18:22:02

US3512217

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered '1985'	System	04 Sep 2020 18:22:02

US3512217

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered 'Jan 1985'	System	04 Sep 2020 18:22:02

US3512217

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered '1985'	System	04 Sep 2020 18:22:02

US3512217

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:55:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Peripheral swelling, LLT: Swelling of legs - version MedDRA\23.0.	Coder Import (b) (4)	04 Sep 2020 20:13:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	04 Sep 2020 20:13:47
Data point term sent to Coder	System	04 Sep 2020 19:31:38
User entered 'BILATERAL LOWER LEG SWELLING'	Allison Crain (b) (4)	04 Sep 2020 19:31:35

US3512217

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'UN Jul 2020'	(b) (4) Allison Crain (b) (4) (b) (4)	04 Sep 2020 19:31:35

US3512217

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered '0'	(b) (4) Allison Crain (b) (4) (b) (4)	04 Sep 2020 19:31:35

US3512217

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:55:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4) (b) (4)	04 Sep 2020 19:31:35

US3512217

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	04 Sep 2020 19:31:35

US3512217

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:55:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered '0'	(b) (4) Allison Crain (b) (4) (b) (4)	04 Sep 2020 19:31:35

US3512217

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered 'Jul 2020'	System	04 Sep 2020 19:31:35

US3512217

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered '2020'	System	04 Sep 2020 19:31:35

US3512217

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered empty.	System	04 Sep 2020 19:31:35

US3512217

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered empty.	System	04 Sep 2020 19:31:35

US3512217

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:55:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	16 Feb 2021 14:38:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Feb 2021 14:38:00
Data point term sent to Coder	System	16 Feb 2021 14:37:24
User entered 'MYOCARDIAL INFARCTION'	Allison Crain (b) (4) (b) (4)	16 Feb 2021 14:36:37

US3512217

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered 'UN UNK 2005'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 14:36:37

US3512217

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered '0'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 14:36:37

US3512217

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:55:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered 'No (N)'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 14:36:37

US3512217

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered 'UN UNK 2005'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 14:36:37

US3512217

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:55:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered '0'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 14:36:37

US3512217

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered 'Jan 2005'	System	16 Feb 2021 14:36:37

US3512217

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered '2005'	System	16 Feb 2021 14:36:37

US3512217

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered 'Jan 2005'	System	16 Feb 2021 14:36:37

US3512217

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered '2005'	System	16 Feb 2021 14:36:37

US3512217

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:55:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Metabolic and nutritional disorders congenital, HLT: Inborn errors of porphyrin metabolism, PT: Porphyria non-acute, LLT: Porphyria cutanea tarda - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 09:25:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 09:25:48
User signature succeeded.	Michael Koren (b) (4) (b) (4)	05 Mar 2021 22:43:41
Data point term sent to Coder	System	02 Mar 2021 11:56:47
User entered 'PORPHYRIA CUTANAE TARDA'	Allison Crain (b) (4) (b) (4)	02 Mar 2021 11:56:28

US3512217

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered 'UN UNK 2014'	(b) (4) Allison Crain (b) (4) (b) (4)	02 Mar 2021 11:56:28

US3512217

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered '0'	(b) (4) Allison Crain (b) (4) (b) (4)	02 Mar 2021 11:56:28

US3512217

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:55:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4) (b) (4)	02 Mar 2021 11:56:28

US3512217

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	02 Mar 2021 11:56:28

US3512217

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:55:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered '0'	(b) (4) Allison Crain (b) (4) (b) (4)	02 Mar 2021 11:56:28

US3512217

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:55:38

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered 'Jan 2014'	System	02 Mar 2021 11:56:28

US3512217

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered '2014'	System	02 Mar 2021 11:56:28

US3512217

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered empty.	System	02 Mar 2021 11:56:28

US3512217

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered empty.	System	02 Mar 2021 11:56:28

US3512217

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:55:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User coded data point as SOC: Cardiac disorders, HLT: Cardiac valve disorders, HLT: Aortic valvular disorders, PT: Aortic valve stenosis, LLT: Aortic valve stenosis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Mar 2021 00:09:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Mar 2021 00:09:46
User signature succeeded.	Michael Koren (b) (4) (b) (4)	05 Mar 2021 22:43:41
Data point term sent to Coder	System	05 Mar 2021 17:19:20
User entered 'MODERATE AORTIC VALVE STENOSIS'	Allison Crain (b) (4) (b) (4)	05 Mar 2021 17:18:33

US3512217

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered '24 Jul 2019'	(b) (4) Allison Crain (b) (4) (b) (4)	05 Mar 2021 17:18:33

US3512217

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered '0'	(b) (4) Allison Crain (b) (4) (b) (4)	05 Mar 2021 17:18:33

US3512217

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:55:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4) (b) (4)	05 Mar 2021 17:18:33

US3512217

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	05 Mar 2021 17:18:33

US3512217

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:55:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered '0'	(b) (4) Allison Crain (b) (4) (b) (4)	05 Mar 2021 17:18:33

US3512217

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered 'Jul 2019'	System	05 Mar 2021 17:18:33

US3512217

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered '2019'	System	05 Mar 2021 17:18:33

US3512217

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered empty.	System	05 Mar 2021 17:18:33

US3512217

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered empty.	System	05 Mar 2021 17:18:33

US3512217

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 07:55:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Cardiac and vascular disorders congenital, HLT: Cardiac valve disorders congenital, PT: Congenital aortic valve incompetence, LLT: Congenital insufficiency of aortic valve - version MedDRA\\23.0.	Coder Import (b) (4)	05 Mar 2021 17:19:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Mar 2021 17:19:55
Data point term sent to Coder	System	05 Mar 2021 17:19:20
User entered 'CONGENITAL AORTIC VALVE INSUFFICIENCY'	Allison Crain (b) (4)	05 Mar 2021 17:19:08

US3512217

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered (b) (6) 1956'	(b) (4) Allison Crain (b) (4) (b) (4)	05 Mar 2021 17:19:08

US3512217

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered '0'	(b) (4) Allison Crain (b) (4) (b) (4)	05 Mar 2021 17:19:08

US3512217

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 07:55:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4) (b) (4)	05 Mar 2021 17:19:08

US3512217

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	05 Mar 2021 17:19:08

US3512217

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 07:55:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:49
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered '0'	(b) (4) Allison Crain (b) (4) (b) (4)	05 Mar 2021 17:19:08

US3512217

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered (b) (6) 1956'	System	05 Mar 2021 17:19:08

US3512217

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered '1956'	System	05 Mar 2021 17:19:08

US3512217

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered empty.	System	05 Mar 2021 17:19:08

US3512217

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered empty.	System	05 Mar 2021 17:19:08

US3512217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:51:00
User entered 'Yes (Y)'	Allison Crain (b) (4)	04 Sep 2020 15:40:03
	(b) (4)	

US3512217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '4 Sep 2020'	Allison Crain (b) (4)	04 Sep 2020 15:40:03

US3512217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:51:00
User entered '10:30'	Allison Crain (b) (4)	04 Sep 2020 15:40:03
	(b) (4)	

US3512217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered '4 Sep 2020 10:30'	System	04 Sep 2020 15:40:03

US3512217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:51:00
User entered '66' in	Allison Crain (b) (4)	04 Sep 2020 15:40:03
DataPoint set to visible.	(b) (4)	
	System	04 Sep 2020 15:37:33

US3512217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:51:00
User entered '174.6' lb	Allison Crain (b) (4)	04 Sep 2020 15:40:03
DataPoint set to visible.	(b) (4)	
	System	04 Sep 2020 15:37:33

US3512217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered '28.24010'	System	04 Sep 2020 15:40:03
DataPoint set to visible.	System	04 Sep 2020 15:37:33

US3512217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered 'kg/m2'	System	04 Sep 2020 15:40:03
DataPoint set to visible.	System	04 Sep 2020 15:37:33

US3512217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:51:00
User entered missing code ND - Not Done.	Allison Crain (b) (4)	04 Sep 2020 15:40:03
	(b) (4)	

US3512217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:51:00
User entered empty.	Allison Crain (b) (4)	04 Sep 2020 15:40:03
	(b) (4)	

US3512217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:51:00
User entered empty.	Allison Crain (b) (4)	04 Sep 2020 15:40:03
	(b) (4)	

US3512217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	06 Oct 2020 16:51:00
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Sep 2020 15:40:03
	Allison Crain (b) (4)	
	(b) (4)	

US3512217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered 'bpm'	System	04 Sep 2020 15:40:03

US3512217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered missing code ND - Not Done.	Allison Crain (b) (4)	04 Sep 2020 15:40:03

US3512217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered 'breaths/min'	System	04 Sep 2020 15:40:03

US3512217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:51:00
User entered missing code ND - Not Done.	Allison Crain (b) (4)	04 Sep 2020 15:40:03
	(b) (4)	

US3512217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered 'mmHg'	System	04 Sep 2020 15:40:03

US3512217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:51:00
User entered missing code ND - Not Done.	Allison Crain (b) (4)	04 Sep 2020 15:40:03
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User entered 'mmHg'	System	04 Sep 2020 15:40:03

US3512217

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20

US3512217

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 07:55:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:51:09
User entered 'Yes (Y)'	Allison Crain (b) (4)	04 Sep 2020 15:39:29
	(b) (4)	

US3512217

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 07:55:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:51:09
User entered '4 Sep 2020'	Allison Crain (b) (4)	04 Sep 2020 15:39:29
	(b) (4)	

US3512217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

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 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:51:46
User entered 'No (N)'	Allison Crain (b) (4)	04 Sep 2020 15:54:35
	(b) (4)	

US3512217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

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 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:51:46
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	04 Sep 2020 15:54:35

US3512217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

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 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:51:46
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	04 Sep 2020 15:54:35

US3512217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

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 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:51:46
User entered 'No (N)'	Allison Crain (b) (4)	04 Sep 2020 15:54:35

US3512217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

[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 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	06 Oct 2020 16:51:46
User entered 'No (N)'	Allison Crain (b) (4)	04 Sep 2020 15:54:35

US3512217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

[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 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:51:46
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	04 Sep 2020 15:54:35

US3512217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

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 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:51:46
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	04 Sep 2020 15:54:35

US3512217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

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 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:51:46
User entered 'No (N)'	Allison Crain (b) (4)	04 Sep 2020 15:54:35

US3512217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

[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 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	06 Oct 2020 16:51:46
User entered 'No (N)'	Allison Crain (b) (4)	04 Sep 2020 15:54:35

US3512217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

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 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:51:46
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	04 Sep 2020 15:54:35

US3512217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

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 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:51:46
User entered 'No (N)'	Allison Crain (b) (4)	04 Sep 2020 15:54:35

US3512217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:51:46
User entered 'No (N)'	Allison Crain (b) (4)	04 Sep 2020 15:54:35
	(b) (4)	

US3512217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:51:46
User entered empty.	Allison Crain (b) (4)	04 Sep 2020 15:54:35
	(b) (4)	

US3512217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered '0'	Allison Crain (b) (4)	04 Sep 2020 15:54:35

US3512217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	06 Oct 2020 16:51:46
User entered '0'	Allison Crain (b) (4)	04 Sep 2020 15:54:35

US3512217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

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 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:51:46
User entered '0'	Allison Crain (b) (4)	04 Sep 2020 15:54:35

US3512217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

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 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:51:46
User entered '0'	Allison Crain (b) (4) (b) (4)	04 Sep 2020 15:54:35

US3512217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

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 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:51:46
User entered '0'	Allison Crain (b) (4)	04 Sep 2020 15:54:35

US3512217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:51:46
User entered 'I'	Allison Crain (b) (4)	04 Sep 2020 15:54:35
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'I'	Allison Crain (b) (4)	04 Sep 2020 15:54:35

US3512217

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:54:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:51:46
User entered 'PLANS ON ROUTINELY GOING TO PLACES WHERE PEOPLE GATHER (GROCERY, RESTAURANTS); INTERACTS W/>5 PEOPLE OUTSIDE OF WORK AND HOME'	Allison Crain (b) (4) (b) (4)	04 Sep 2020 15:54:35

US3512217

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:51:51
User entered 'Yes (Y)'	Allison Crain (b) (4)	04 Sep 2020 15:37:43
	(b) (4)	

US3512217

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '4 Sep 2020'	Allison Crain (b) (4)	04 Sep 2020 15:37:43

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[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 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Clinic (Clinic)'	Allison Crain (b) (4)	04 Sep 2020 15:37:43

US3512217

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'VISIT1'	System	04 Sep 2020 15:37:43

US3512217

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	06 Oct 2020 16:51:56
User entered '04 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 14:59:30

US3512217

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:55:38

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	06 Oct 2020 16:51:56
User entered '111543'	(b) (4), (b) (6)	04 Sep 2020 14:59:30
	RWS_ENDPOINT	
	ENDPOINT (b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	06 Oct 2020 16:51:56
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 14:59:30

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:55:38

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)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:51:56
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	04 Sep 2020 15:38:54

US3512217

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:55:38

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)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:51:56
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	04 Sep 2020 15:38:54

US3512217

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:51:56
User entered 'No (N)'	Allison Crain (b) (4)	04 Sep 2020 15:38:54
	(b) (4)	

US3512217

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'No (N)'	Allison Crain (b) (4)	04 Sep 2020 15:38:54

US3512217

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:55:38

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:51:56
User entered 'No (N)'	Allison Crain (b) (4)	04 Sep 2020 15:38:54
	(b) (4)	

US3512217

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:55:38

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:55:25
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 12:06:51
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'Completed' (Site from DM).	Allison Crain (b) (4)	04 Nov 2020 17:56:14
User entered 'No (N)'	Allison Crain (b) (4)	04 Nov 2020 17:56:11
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 14:59:41
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:22:39
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:22:38

US3512217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:55:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:52:40
User entered missing code ND - Not Done.	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:08:54

US3512217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:55:38

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:52:40
User entered missing code ND - Not Done.	Taylor Johnson (b) (4)	04 Sep 2020 18:08:54
	(b) (4)	

US3512217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:55:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:52:40
User entered missing code ND - Not Done.	Taylor Johnson (b) (4)	04 Sep 2020 18:08:54
	(b) (4)	

US3512217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:55:38

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:52:40
User entered missing code ND - Not Done.	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:08:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User accepted default value 'Pre-Dose (PREDOSE)'	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:08:54

US3512217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:52:40
User entered 'Yes (Y)'	Taylor Johnson (b) (4)	04 Sep 2020 18:08:54
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:52:40
User entered '04 Sep 2020'	Taylor Johnson (b) (4)	04 Sep 2020 18:08:54
	(b) (4)	

US3512217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:52:40
User entered '10:30'	Taylor Johnson (b) (4)	04 Sep 2020 18:08:54
	(b) (4)	

US3512217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered '04 Sep 2020 10:30'	System	04 Sep 2020 18:08:54

US3512217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:52:40
User entered '98.6' F	Taylor Johnson (b) (4)	04 Sep 2020 18:08:54
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:52:40
User entered 'Oral (Oral)'	Taylor Johnson (b) (4)	04 Sep 2020 18:08:54
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:52:40
User entered empty.	Taylor Johnson (b) (4)	04 Sep 2020 18:08:54
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:52:40
User entered '68'	Taylor Johnson (b) (4)	04 Sep 2020 18:08:54
	(b) (4)	

US3512217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'bpm'	System	04 Sep 2020 18:08:54

US3512217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:52:40
User entered '12'	Taylor Johnson (b) (4)	04 Sep 2020 18:08:54
	(b) (4)	

US3512217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'breaths/min'	System	04 Sep 2020 18:08:54

US3512217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:52:40
User entered '119'	Taylor Johnson (b) (4)	04 Sep 2020 18:08:54
	(b) (4)	

US3512217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'mmHg'	System	04 Sep 2020 18:08:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:52:40
User entered '68'	Taylor Johnson (b) (4)	04 Sep 2020 18:08:54
	(b) (4)	

US3512217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'mmHg'	System	04 Sep 2020 18:08:54

US3512217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:55:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:52:40
User entered missing code ND - Not Done.	Taylor Johnson (b) (4)	04 Sep 2020 18:08:54
	(b) (4)	

US3512217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:55:38

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:52:40
User entered missing code ND - Not Done.	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:08:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User accepted default value 'Post-Dose (POSTDOSE)'	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:08:54

US3512217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Yes (Y)'	Taylor Johnson (b) (4)	04 Sep 2020 18:08:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:52:40
User entered '04 Sep 2020'	Taylor Johnson (b) (4)	04 Sep 2020 18:08:54
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:52:40
User entered '11:59'	Taylor Johnson (b) (4)	04 Sep 2020 18:08:54
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered '04 Sep 2020 11:59'	System	04 Sep 2020 18:08:54

US3512217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:52:40
User entered '98.3' F	Taylor Johnson (b) (4)	04 Sep 2020 18:08:54
	(b) (4)	

US3512217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:52:40
User entered 'Oral (Oral)'	Taylor Johnson (b) (4)	04 Sep 2020 18:08:54
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:52:40
User entered empty.	Taylor Johnson (b) (4)	04 Sep 2020 18:08:54
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:52:40
User entered '61'	Taylor Johnson (b) (4)	04 Sep 2020 18:08:54
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'bpm'	System	04 Sep 2020 18:08:54

US3512217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:52:40
User entered '12'	Taylor Johnson (b) (4)	04 Sep 2020 18:08:54
	(b) (4)	

US3512217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'breaths/min'	System	04 Sep 2020 18:08:54

US3512217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:52:40
User entered '127'	Taylor Johnson (b) (4)	04 Sep 2020 18:08:54
	(b) (4)	

US3512217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'mmHg'	System	04 Sep 2020 18:08:54

US3512217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:52:40
User entered '65'	Taylor Johnson (b) (4)	04 Sep 2020 18:08:54
	(b) (4)	

US3512217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'mmHg'	System	04 Sep 2020 18:08:54

US3512217

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 07:55:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'No (N)'	Allison Crain (b) (4)	04 Sep 2020 15:39:06

US3512217

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 07:55:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Allison Crain (b) (4)	04 Sep 2020 15:39:06

US3512217

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:52:53
User entered 'Yes (Y)'	Allison Crain (b) (4)	04 Sep 2020 15:55:40
	(b) (4)	

US3512217

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:52:53
User entered empty.	Allison Crain (b) (4)	04 Sep 2020 15:55:40
	(b) (4)	

US3512217

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

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)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:52:53
User entered empty.	Allison Crain (b) (4) (b) (4)	04 Sep 2020 15:55:40

US3512217

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 15:55:40

US3512217

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:52:53
User entered '4 Sep 2020'	Allison Crain (b) (4)	04 Sep 2020 15:55:40
	(b) (4)	

US3512217

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:52:53
User entered '11:28'	Allison Crain (b) (4)	04 Sep 2020 15:55:40
	(b) (4)	

US3512217

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered '4 Sep 2020 11:28'	System	04 Sep 2020 15:55:40

US3512217

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:52:53
User entered 'Left Arm (LEFT ARM)'	Allison Crain (b) (4)	04 Sep 2020 15:55:40
	(b) (4)	

US3512217

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:52:53
User entered 'ONCE'	System	04 Sep 2020 15:55:40

US3512217

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 15:55:40

US3512217

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:53:00
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	04 Sep 2020 15:49:24

US3512217

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '4 Sep 2020'	Allison Crain (b) (4)	04 Sep 2020 15:49:24
	(b) (4)	

US3512217

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '11:06'	Allison Crain (b) (4)	04 Sep 2020 15:49:24

US3512217

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered '4 Sep 2020 11:06'	System	04 Sep 2020 15:49:24

US3512217

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 07:55:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '4 Sep 2020'	Allison Crain (b) (4)	06 Oct 2020 16:53:11
	(b) (4)	04 Sep 2020 15:49:34

US3512217

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:55:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Allison Crain (b) (4) (b) (4)	04 Sep 2020 15:49:34

US3512217

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:55:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:53:11
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	04 Sep 2020 15:49:34

US3512217

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:55:38

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:53:11
User entered '11:00'	Allison Crain (b) (4) (b) (4)	04 Sep 2020 15:49:34

US3512217

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered '4 Sep 2020 11:00'	System	04 Sep 2020 15:49:34

US3512217

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:55:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Allison Crain (b) (4) (b) (4)	04 Sep 2020 15:49:34

US3512217

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:55:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:53:11
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	04 Sep 2020 15:49:34

US3512217

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:55:38

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:53:11
User entered empty.	Allison Crain (b) (4) (b) (4)	04 Sep 2020 15:49:34

US3512217

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:55:38

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered empty.	System	04 Sep 2020 15:49:34

US3512217

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	06 Oct 2020 16:53:17
User entered 'Yes (Y)'	Allison Crain (b) (4)	04 Sep 2020 15:40:15

US3512217

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'I'	System	04 Sep 2020 15:40:15

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	04 Sep 2020 15:55:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-04T11:59:29', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'a69a6ee0-8f95-4564-825c-25b1563a4cd8' User entered 'Yes (Y)'	System	04 Sep 2020 16:00:29
	System	04 Sep 2020 16:00:29

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-04T11:59:45', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'a69a6ee0-8f95-4564-825c-25b1563a4cd8' User entered '98.3'	System	04 Sep 2020 16:00:29
	System	04 Sep 2020 16:00:29

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-04T11:59:56', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'a69a6ee0-8f95-4564-825c-25b1563a4cd8'	System	04 Sep 2020 16:00:29
User entered 'No (N)'	System	04 Sep 2020 16:00:29

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-04T12:00:22', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'a69a6ee0-8f95-4564-825c-25b1563a4cd8' User entered '04 Sep 2020 12:00'	System	04 Sep 2020 16:00:29
	System	04 Sep 2020 16:00:29

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '04 Sep 2020 11:48'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '04 Sep 2020 14:18'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	04 Sep 2020 15:55:40
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-04T21:53:58', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'ac9a5606-d267-4808-9f65-0740810b9242' User entered 'Yes (Y)'	System	05 Sep 2020 01:54:32
	System	05 Sep 2020 01:54:32

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-04T21:54:06', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'ac9a5606-d267-4808-9f65-0740810b9242' User entered '98.1'	System	05 Sep 2020 01:54:32
	System	05 Sep 2020 01:54:32

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-04T21:54:22', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'ac9a5606-d267-4808-9f65-0740810b9242'	System	05 Sep 2020 01:54:32
User entered 'No (N)'	System	05 Sep 2020 01:54:32

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-04T21:54:28', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'ac9a5606-d267-4808-9f65-0740810b9242'	System	05 Sep 2020 01:54:32
User entered '04 Sep 2020 21:54'	System	05 Sep 2020 01:54:32

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '04 Sep 2020 15:13'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	04 Sep 2020 15:55:40
User entered 'Day 2'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-05T19:04:20', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '8203ddb9-0d9b-47a5-9e55-b802902445a9' User entered 'Yes (Y)'	System	05 Sep 2020 23:04:59
	System	05 Sep 2020 23:04:59

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-05T19:04:34', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '8203ddb9-0d9b-47a5-9e55-b802902445a9' User entered '98.3'	System	05 Sep 2020 23:04:59
	System	05 Sep 2020 23:04:59

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-05T19:04:41', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '8203ddb9-0d9b-47a5-9e55-b802902445a9' User entered 'No (N)'	System	05 Sep 2020 23:04:59
	System	05 Sep 2020 23:04:59

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-05T19:04:56', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '8203ddb9-0d9b-47a5-9e55-b802902445a9' User entered '05 Sep 2020 19:04'	System	05 Sep 2020 23:04:59
	System	05 Sep 2020 23:04:59

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	04 Sep 2020 15:55:40
User entered 'Day 3'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-06T18:07:40', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '26b4d41c-abe9-413f-9c33-5e002a53e141' User entered 'Yes (Y)'	System	06 Sep 2020 22:08:57
	System	06 Sep 2020 22:08:57

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-06T18:08:40', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '26b4d41c-abe9-413f-9c33-5e002a53e141' User entered '97.6'	System	06 Sep 2020 22:08:57
	System	06 Sep 2020 22:08:57

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-06T18:08:47', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '26b4d41c-abe9-413f-9c33-5e002a53e141' User entered 'No (N)'	System	06 Sep 2020 22:08:57
	System	06 Sep 2020 22:08:57

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-06T18:08:52', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '26b4d41c-abe9-413f-9c33-5e002a53e141' User entered '06 Sep 2020 18:08'	System	06 Sep 2020 22:08:57
	System	06 Sep 2020 22:08:57

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	04 Sep 2020 15:55:40
User entered 'Day 4'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-07T21:31:30', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'ba696b8e-3a45-41df-a4b2-45f7072ebeac' User entered 'Yes (Y)'	System	08 Sep 2020 01:31:54
	System	08 Sep 2020 01:31:54

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-07T21:31:39', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'ba696b8e-3a45-41df-a4b2-45f7072ebeac' User entered '97.6'	System	08 Sep 2020 01:31:54
	System	08 Sep 2020 01:31:54

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-07T21:31:49', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'ba696b8e-3a45-41df-a4b2-45f7072ebeac'	System	08 Sep 2020 01:31:54
User entered 'No (N)'	System	08 Sep 2020 01:31:54

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-07T21:31:53', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'ba696b8e-3a45-41df-a4b2-45f7072ebeac'	System	08 Sep 2020 01:31:54
User entered '07 Sep 2020 21:31'	System	08 Sep 2020 01:31:54

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	04 Sep 2020 15:55:40
User entered 'Day 5'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-08T22:56:22', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '92b33ede-ba7f-4d0c-a66a-9771eb90f904' User entered 'Yes (Y)'	System	09 Sep 2020 02:56:39
	System	09 Sep 2020 02:56:39

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-08T22:56:28', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '92b33ede-ba7f-4d0c-a66a-9771eb90f904' User entered '98.6'	System	09 Sep 2020 02:56:39
	System	09 Sep 2020 02:56:39

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-08T22:56:32', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '92b33ede-ba7f-4d0c-a66a-9771eb90f904' User entered 'No (N)'	System	09 Sep 2020 02:56:39
	System	09 Sep 2020 02:56:39

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-08T22:56:36', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '92b33ede-ba7f-4d0c-a66a-9771eb90f904' User entered '08 Sep 2020 22:56'	System	09 Sep 2020 02:56:39
	System	09 Sep 2020 02:56:39

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	04 Sep 2020 15:55:40
User entered 'Day 6'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-09T18:02:13', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '7ea73ab9-f0eb-4589-9b28-2a02c41745ba' User entered 'Yes (Y)'	System	09 Sep 2020 22:03:05
	System	09 Sep 2020 22:03:05

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-09T18:02:45', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '7ea73ab9-f0eb-4589-9b28-2a02c41745ba' User entered '98.5'	System	09 Sep 2020 22:03:05
	System	09 Sep 2020 22:03:05

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-09T18:02:53', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '7ea73ab9-f0eb-4589-9b28-2a02c41745ba' User entered 'No (N)'	System	09 Sep 2020 22:03:05
	System	09 Sep 2020 22:03:05

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-09T18:02:56', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '7ea73ab9-f0eb-4589-9b28-2a02c41745ba' User entered '09 Sep 2020 18:02'	System	09 Sep 2020 22:03:05
	System	09 Sep 2020 22:03:05

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	04 Sep 2020 15:55:40
User entered 'Day 7'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-10T18:40:02', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '81bbe784-8609-451e-b687-f549c6e9d1cc' User entered 'Yes (Y)'	System	10 Sep 2020 22:40:19
	System	10 Sep 2020 22:40:19

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-10T18:40:09', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '81bbe784-8609-451e-b687-f549c6e9d1cc' User entered '98.3'	System	10 Sep 2020 22:40:19
	System	10 Sep 2020 22:40:19

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-10T18:40:12', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '81bbe784-8609-451e-b687-f549c6e9d1cc' User entered 'No (N)'	System	10 Sep 2020 22:40:19
	System	10 Sep 2020 22:40:19

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-10T18:40:15', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '81bbe784-8609-451e-b687-f549c6e9d1cc' User entered '10 Sep 2020 18:40'	System	10 Sep 2020 22:40:19
	System	10 Sep 2020 22:40:19

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	04 Sep 2020 15:55:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-04T12:03:44', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '78b03a12-8a26-4573-874f-6479ffbdc40c' User entered 'None (1)'	System	04 Sep 2020 16:06:01
	System	04 Sep 2020 16:06:01

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-04T12:03:59', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '78b03a12-8a26-4573-874f-6479fffdc40c' User entered 'No (N)'	System	04 Sep 2020 16:06:01
	System	04 Sep 2020 16:06:01

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-04T12:04:05', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '78b03a12-8a26-4573-874f-6479fffdc40c' User entered 'No (N)'	System	04 Sep 2020 16:06:01
	System	04 Sep 2020 16:06:01

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-04T12:04:12', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '78b03a12-8a26-4573-874f-6479ffbdc40c' User entered 'None (1)'	System	04 Sep 2020 16:06:01
	System	04 Sep 2020 16:06:01

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-04T12:04:15', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '78b03a12-8a26-4573-874f-6479fffdc40c' User entered '04 Sep 2020 12:04'	System	04 Sep 2020 16:06:01
	System	04 Sep 2020 16:06:01

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '04 Sep 2020 11:48'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '04 Sep 2020 14:18'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	04 Sep 2020 15:55:40
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-04T21:54:38', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '9467afb3-141d-4bf3-a178-7ac2a3e59a78' User entered 'None (1)'	System	05 Sep 2020 01:55:29
	System	05 Sep 2020 01:55:29

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-04T21:55:02', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '9467afb3-141d-4bf3-a178-7ac2a3e59a78' User entered 'No (N)'	System	05 Sep 2020 01:55:29
	System	05 Sep 2020 01:55:29

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-04T21:55:08', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '9467afb3-141d-4bf3-a178-7ac2a3e59a78' User entered 'No (N)'	System	05 Sep 2020 01:55:29
	System	05 Sep 2020 01:55:29

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-04T21:55:20', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '9467afb3-141d-4bf3-a178-7ac2a3e59a78' User entered 'None (1)'	System	05 Sep 2020 01:55:29
	System	05 Sep 2020 01:55:29

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-04T21:55:24', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '9467afb3-141d-4bf3-a178-7ac2a3e59a78' User entered '04 Sep 2020 21:55'	System	05 Sep 2020 01:55:29
	System	05 Sep 2020 01:55:29

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '04 Sep 2020 15:13'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	04 Sep 2020 15:55:40
User entered 'Day 2'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:55:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-05T19:05:38', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '7fd0232c-5ea3-47c7-aa3e-9d22d66ae464'	System	05 Sep 2020 23:06:12
User entered 'None (1)'	System	05 Sep 2020 23:06:12

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-05T19:05:42', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '7fd0232c-5ea3-47c7-aa3e-9d22d66ae464' User entered 'No (N)'	System	05 Sep 2020 23:06:12
	System	05 Sep 2020 23:06:12

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-05T19:05:50', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '7fd0232c-5ea3-47c7-aa3e-9d22d66ae464' User entered 'No (N)'	System	05 Sep 2020 23:06:12
	System	05 Sep 2020 23:06:12

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:55:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-05T19:06:06', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '7fd0232c-5ea3-47c7-aa3e-9d22d66ae464'	System	05 Sep 2020 23:06:12
User entered 'None (1)'	System	05 Sep 2020 23:06:12

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-05T19:06:09', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '7fd0232c-5ea3-47c7-aa3e-9d22d66ae464' User entered '05 Sep 2020 19:06'	System	05 Sep 2020 23:06:12
	System	05 Sep 2020 23:06:12

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	04 Sep 2020 15:55:40
User entered 'Day 3'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:55:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-06T18:09:31', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '6b4855b6-4efb-4e28-8aea-d5728a8bb524'	System	06 Sep 2020 22:10:10
User entered 'None (1)'	System	06 Sep 2020 22:10:10

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-06T18:09:48', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '6b4855b6-4efb-4e28-8aea-d5728a8bb524' User entered 'No (N)'	System	06 Sep 2020 22:10:10
	System	06 Sep 2020 22:10:10

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-06T18:09:58', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '6b4855b6-4efb-4e28-8aea-d5728a8bb524' User entered 'No (N)'	System	06 Sep 2020 22:10:10
	System	06 Sep 2020 22:10:10

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:55:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-06T18:10:02', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '6b4855b6-4efb-4e28-8aea-d5728a8bb524' User entered 'None (1)'	System	06 Sep 2020 22:10:10
	System	06 Sep 2020 22:10:10

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-06T18:10:06', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '6b4855b6-4efb-4e28-8aea-d5728a8bb524' User entered '06 Sep 2020 18:10'	System	06 Sep 2020 22:10:10
	System	06 Sep 2020 22:10:10

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	04 Sep 2020 15:55:40
User entered 'Day 4'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:55:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-07T21:31:58', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'addcfdbc-c530-496f-8ea3-bf16a2a7ffc3'	System	08 Sep 2020 01:32:13
User entered 'None (1)'	System	08 Sep 2020 01:32:13

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-07T21:32:01', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'addcfdbc-c530-496f-8ea3-bf16a2a7ffc3'	System	08 Sep 2020 01:32:13
User entered 'No (N)'	System	08 Sep 2020 01:32:13

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-07T21:32:03', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'addcfdbc-c530-496f-8ea3-bf16a2a7ffc3'	System	08 Sep 2020 01:32:13
User entered 'No (N)'	System	08 Sep 2020 01:32:13

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:55:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-07T21:32:06', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'addcfdbc-c530-496f-8ea3-bf16a2a7ffc3' User entered 'None (1)'	System	08 Sep 2020 01:32:13
	System	08 Sep 2020 01:32:13

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-07T21:32:08', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'addcfdbc-c530-496f-8ea3-bf16a2a7ffc3'	System	08 Sep 2020 01:32:13
User entered '07 Sep 2020 21:32'	System	08 Sep 2020 01:32:13

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	04 Sep 2020 15:55:40
User entered 'Day 5'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:55:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-08T22:56:40', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '4257eef8-f3aa-409b-b32c-638e659b4fbb' User entered 'None (1)'	System	09 Sep 2020 02:56:53
	System	09 Sep 2020 02:56:53

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-08T22:56:43', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '4257eef8-f3aa-409b-b32c-638e659b4fbb' User entered 'No (N)'	System	09 Sep 2020 02:56:53
	System	09 Sep 2020 02:56:53

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-08T22:56:45', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '4257eef8-f3aa-409b-b32c-638e659b4fbb' User entered 'No (N)'	System	09 Sep 2020 02:56:53
	System	09 Sep 2020 02:56:53

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:55:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-08T22:56:47', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '4257eef8-f3aa-409b-b32c-638e659b4fbb'	System	09 Sep 2020 02:56:53
User entered 'None (1)'	System	09 Sep 2020 02:56:53

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-08T22:56:50', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '4257eef8-f3aa-409b-b32c-638e659b4fbb' User entered '08 Sep 2020 22:56'	System	09 Sep 2020 02:56:53
	System	09 Sep 2020 02:56:53

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	04 Sep 2020 15:55:40
User entered 'Day 6'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:55:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-09T18:03:02', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '977b75ca-9129-46e9-86ec-ba6e9192b4d5' User entered 'None (1)'	System	09 Sep 2020 22:03:50
	System	09 Sep 2020 22:03:50

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-09T18:03:07', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '977b75ca-9129-46e9-86ec-ba6e9192b4d5' User entered 'No (N)'	System	09 Sep 2020 22:03:50
	System	09 Sep 2020 22:03:50

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-09T18:03:42', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '977b75ca-9129-46e9-86ec-ba6e9192b4d5' User entered 'No (N)'	System	09 Sep 2020 22:03:50
	System	09 Sep 2020 22:03:50

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:55:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-09T18:03:46', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '977b75ca-9129-46e9-86ec-ba6e9192b4d5' User entered 'None (1)'	System	09 Sep 2020 22:03:50
	System	09 Sep 2020 22:03:50

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-09T18:03:49', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '977b75ca-9129-46e9-86ec-ba6e9192b4d5' User entered '09 Sep 2020 18:03'	System	09 Sep 2020 22:03:50
	System	09 Sep 2020 22:03:50

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	04 Sep 2020 15:55:40
User entered 'Day 7'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:55:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-10T18:40:20', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '938a2f39-0fcd-499d-86a5-01bea47a88a0' User entered 'None (1)'	System	10 Sep 2020 22:40:37
	System	10 Sep 2020 22:40:37

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-10T18:40:25', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '938a2f39-0fcd-499d-86a5-01bea47a88a0' User entered 'No (N)'	System	10 Sep 2020 22:40:37
	System	10 Sep 2020 22:40:37

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-10T18:40:28', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '938a2f39-0fcd-499d-86a5-01bea47a88a0' User entered 'No (N)'	System	10 Sep 2020 22:40:37
	System	10 Sep 2020 22:40:37

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:55:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-10T18:40:30', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '938a2f39-0fcd-499d-86a5-01bea47a88a0' User entered 'None (1)'	System	10 Sep 2020 22:40:37
	System	10 Sep 2020 22:40:37

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-10T18:40:33', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '938a2f39-0fcd-499d-86a5-01bea47a88a0' User entered '10 Sep 2020 18:40'	System	10 Sep 2020 22:40:37
	System	10 Sep 2020 22:40:37

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	04 Sep 2020 15:55:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-04T12:01:00', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '6a458eed-0819-4707-ac29-9d28ab93a671' User entered 'None (0)'	System	04 Sep 2020 16:05:15
	System	04 Sep 2020 16:05:15

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-04T12:02:22', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '6a458eed-0819-4707-ac29-9d28ab93a671' User entered 'None (0)'	System	04 Sep 2020 16:05:15
	System	04 Sep 2020 16:05:15

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-04T12:02:35', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '6a458eed-0819-4707-ac29-9d28ab93a671' User entered 'None (0)'	System	04 Sep 2020 16:05:15
	System	04 Sep 2020 16:05:15

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-04T12:02:47', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '6a458eed-0819-4707-ac29-9d28ab93a671' User entered 'None (0)'	System	04 Sep 2020 16:05:15
	System	04 Sep 2020 16:05:15

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-04T12:02:54', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '6a458eed-0819-4707-ac29-9d28ab93a671' User entered 'None (0)'	System	04 Sep 2020 16:05:15
	System	04 Sep 2020 16:05:15

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-04T12:03:01', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '6a458eed-0819-4707-ac29-9d28ab93a671' User entered 'None (0)'	System	04 Sep 2020 16:05:15
	System	04 Sep 2020 16:05:15

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

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)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-04T12:03:18', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '6a458eed-0819-4707-ac29-9d28ab93a671' User entered 'No (N)'	System	04 Sep 2020 16:05:15
	System	04 Sep 2020 16:05:15

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-04T12:03:22', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '6a458eed-0819-4707-ac29-9d28ab93a671' User entered '04 Sep 2020 12:03'	System	04 Sep 2020 16:05:15
	System	04 Sep 2020 16:05:15

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '04 Sep 2020 11:48'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '04 Sep 2020 14:18'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	04 Sep 2020 15:55:40
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-04T21:55:34', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'dc5eafe4-5cd0-4c9d-948a-e7fd983a0443' User entered 'None (0)'	System	05 Sep 2020 01:56:23
	System	05 Sep 2020 01:56:23

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-04T21:55:40', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'dc5eafe4-5cd0-4c9d-948a-e7fd983a0443' User entered 'None (0)'	System	05 Sep 2020 01:56:23
	System	05 Sep 2020 01:56:23

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-04T21:55:48', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'dc5eafe4-5cd0-4c9d-948a-e7fd983a0443' User entered 'None (0)'	System	05 Sep 2020 01:56:23
	System	05 Sep 2020 01:56:23

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-04T21:55:55', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'dc5eafe4-5cd0-4c9d-948a-e7fd983a0443' User entered 'None (0)'	System	05 Sep 2020 01:56:23
	System	05 Sep 2020 01:56:23

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-04T21:56:01', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'dc5eafe4-5cd0-4c9d-948a-e7fd983a0443' User entered 'None (0)'	System	05 Sep 2020 01:56:23
	System	05 Sep 2020 01:56:23

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-04T21:56:07', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'dc5eafe4-5cd0-4c9d-948a-e7fd983a0443' User entered 'None (0)'	System	05 Sep 2020 01:56:23
	System	05 Sep 2020 01:56:23

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

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)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-04T21:56:16', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'dc5eafe4-5cd0-4c9d-948a-e7fd983a0443'	System	05 Sep 2020 01:56:23
User entered 'No (N)'	System	05 Sep 2020 01:56:23

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-04T21:56:19', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'dc5eafe4-5cd0-4c9d-948a-e7fd983a0443'	System	05 Sep 2020 01:56:23
User entered '04 Sep 2020 21:56'	System	05 Sep 2020 01:56:23

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '04 Sep 2020 15:13'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	04 Sep 2020 15:55:40
User entered 'Day 2'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:55:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-05T19:06:15', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'fc21fa70-fc06-418b-83cd-ebcc1d968e93' User entered 'None (0)'	System	05 Sep 2020 23:06:54
	System	05 Sep 2020 23:06:54

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:55:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-05T19:06:19', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'fc21fa70-fc06-418b-83cd-ebcc1d968e93' User entered 'None (0)'	System	05 Sep 2020 23:06:54
	System	05 Sep 2020 23:06:54

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-05T19:06:25', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'fc21fa70-fc06-418b-83cd-ebcc1d968e93' User entered 'None (0)'	System	05 Sep 2020 23:06:54
	System	05 Sep 2020 23:06:54

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-05T19:06:32', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'fc21fa70-fc06-418b-83cd-ebcc1d968e93' User entered 'None (0)'	System	05 Sep 2020 23:06:54
	System	05 Sep 2020 23:06:54

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-05T19:06:36', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'fc21fa70-fc06-418b-83cd-ebcc1d968e93' User entered 'None (0)'	System	05 Sep 2020 23:06:54
	System	05 Sep 2020 23:06:54

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:55:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-05T19:06:40', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'fc21fa70-fc06-418b-83cd-ebcc1d968e93' User entered 'None (0)'	System	05 Sep 2020 23:06:54
	System	05 Sep 2020 23:06:54

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:55:38

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)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-05T19:06:48', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'fc21fa70-fc06-418b-83cd-ebcc1d968e93' User entered 'No (N)'	System	05 Sep 2020 23:06:54
	System	05 Sep 2020 23:06:54

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-05T19:06:51', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'fc21fa70-fc06-418b-83cd-ebcc1d968e93' User entered '05 Sep 2020 19:06'	System	05 Sep 2020 23:06:54
	System	05 Sep 2020 23:06:54

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	04 Sep 2020 15:55:40
User entered 'Day 3'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:55:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-06T18:10:12', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '713ed213-e9d8-43c8-a48b-30bff294a9fc' User entered 'None (0)'	System	06 Sep 2020 22:11:09
	System	06 Sep 2020 22:11:09

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:55:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-06T18:10:18', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '713ed213-e9d8-43c8-a48b-30bff294a9fc' User entered 'None (0)'	System	06 Sep 2020 22:11:09
	System	06 Sep 2020 22:11:09

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-06T18:10:40', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '713ed213-e9d8-43c8-a48b-30bff294a9fc' User entered 'None (0)'	System	06 Sep 2020 22:11:09
	System	06 Sep 2020 22:11:09

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-06T18:10:45', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '713ed213-e9d8-43c8-a48b-30bff294a9fc' User entered 'None (0)'	System	06 Sep 2020 22:11:09
	System	06 Sep 2020 22:11:09

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-06T18:10:48', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '713ed213-e9d8-43c8-a48b-30bff294a9fc' User entered 'None (0)'	System	06 Sep 2020 22:11:09
	System	06 Sep 2020 22:11:09

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:55:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-06T18:10:53', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '713ed213-e9d8-43c8-a48b-30bff294a9fc' User entered 'None (0)'	System	06 Sep 2020 22:11:09
	System	06 Sep 2020 22:11:09

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:55:38

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)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-06T18:11:04', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '713ed213-e9d8-43c8-a48b-30bff294a9fc' User entered 'No (N)'	System	06 Sep 2020 22:11:09
	System	06 Sep 2020 22:11:09

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-06T18:11:07', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '713ed213-e9d8-43c8-a48b-30bff294a9fc' User entered '06 Sep 2020 18:11'	System	06 Sep 2020 22:11:09
	System	06 Sep 2020 22:11:09

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	04 Sep 2020 15:55:40
User entered 'Day 4'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:55:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-07T21:32:13', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'e99d3f53-dea9-449f-a4cd-60ed5b312898' User entered 'None (0)'	System	08 Sep 2020 01:32:54
	System	08 Sep 2020 01:32:54

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:55:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-07T21:32:15', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'e99d3f53-dea9-449f-a4cd-60ed5b312898' User entered 'None (0)'	System	08 Sep 2020 01:32:54
	System	08 Sep 2020 01:32:54

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-07T21:32:18', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'e99d3f53-dea9-449f-a4cd-60ed5b312898' User entered 'None (0)'	System	08 Sep 2020 01:32:54
	System	08 Sep 2020 01:32:54

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-07T21:32:20', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'e99d3f53-dea9-449f-a4cd-60ed5b312898' User entered 'None (0)'	System	08 Sep 2020 01:32:54
	System	08 Sep 2020 01:32:54

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-07T21:32:22', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'e99d3f53-dea9-449f-a4cd-60ed5b312898' User entered 'None (0)'	System	08 Sep 2020 01:32:54
	System	08 Sep 2020 01:32:54

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:55:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-07T21:32:24', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'e99d3f53-dea9-449f-a4cd-60ed5b312898' User entered 'None (0)'	System	08 Sep 2020 01:32:54
	System	08 Sep 2020 01:32:54

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:55:38

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)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-07T21:32:33', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'e99d3f53-dea9-449f-a4cd-60ed5b312898'	System	08 Sep 2020 01:32:54
User entered 'No (N)'	System	08 Sep 2020 01:32:54

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-07T21:32:52', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'e99d3f53-dea9-449f-a4cd-60ed5b312898' User entered '07 Sep 2020 21:32'	System	08 Sep 2020 01:32:54
	System	08 Sep 2020 01:32:54

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	04 Sep 2020 15:55:40
User entered 'Day 5'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:55:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-08T22:56:57', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '44151ae1-6253-432a-838c-202ee54ce113' User entered 'None (0)'	System	09 Sep 2020 02:57:20
	System	09 Sep 2020 02:57:20

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:55:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-08T22:56:59', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '44151ae1-6253-432a-838c-202ee54ce113' User entered 'None (0)'	System	09 Sep 2020 02:57:20
	System	09 Sep 2020 02:57:20

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-08T22:57:01', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '44151ae1-6253-432a-838c-202ee54ce113' User entered 'None (0)'	System	09 Sep 2020 02:57:20
	System	09 Sep 2020 02:57:20

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-08T22:57:04', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '44151ae1-6253-432a-838c-202ee54ce113' User entered 'None (0)'	System	09 Sep 2020 02:57:20
	System	09 Sep 2020 02:57:20

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-08T22:57:07', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '44151ae1-6253-432a-838c-202ee54ce113' User entered 'None (0)'	System	09 Sep 2020 02:57:20
	System	09 Sep 2020 02:57:20

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:55:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-08T22:57:10', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '44151ae1-6253-432a-838c-202ee54ce113' User entered 'None (0)'	System	09 Sep 2020 02:57:20
	System	09 Sep 2020 02:57:20

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:55:38

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)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-08T22:57:14', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '44151ae1-6253-432a-838c-202ee54ce113' User entered 'No (N)'	System	09 Sep 2020 02:57:20
	System	09 Sep 2020 02:57:20

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-08T22:57:17', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '44151ae1-6253-432a-838c-202ee54ce113' User entered '08 Sep 2020 22:57'	System	09 Sep 2020 02:57:20
	System	09 Sep 2020 02:57:20

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	04 Sep 2020 15:55:40
User entered 'Day 6'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:55:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-09T18:03:54', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '4b062cdc-0c48-49db-ba67-6c3f362e1c2b' User entered 'None (0)'	System	09 Sep 2020 22:04:24
	System	09 Sep 2020 22:04:24

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:55:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-09T18:03:57', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '4b062cdc-0c48-49db-ba67-6c3f362e1c2b' User entered 'None (0)'	System	09 Sep 2020 22:04:24
	System	09 Sep 2020 22:04:24

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-09T18:04:00', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '4b062cdc-0c48-49db-ba67-6c3f362e1c2b' User entered 'None (0)'	System	09 Sep 2020 22:04:24
	System	09 Sep 2020 22:04:24

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-09T18:04:07', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '4b062cdc-0c48-49db-ba67-6c3f362e1c2b' User entered 'None (0)'	System	09 Sep 2020 22:04:24
	System	09 Sep 2020 22:04:24

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-09T18:04:10', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '4b062cdc-0c48-49db-ba67-6c3f362e1c2b' User entered 'None (0)'	System	09 Sep 2020 22:04:24
	System	09 Sep 2020 22:04:24

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:55:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-09T18:04:13', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '4b062cdc-0c48-49db-ba67-6c3f362e1c2b' User entered 'None (0)'	System	09 Sep 2020 22:04:24
	System	09 Sep 2020 22:04:24

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:55:38

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)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-09T18:04:18', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '4b062cdc-0c48-49db-ba67-6c3f362e1c2b' User entered 'No (N)'	System	09 Sep 2020 22:04:24
	System	09 Sep 2020 22:04:24

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-09T18:04:21', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '4b062cdc-0c48-49db-ba67-6c3f362e1c2b' User entered '09 Sep 2020 18:04'	System	09 Sep 2020 22:04:24
	System	09 Sep 2020 22:04:24

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	04 Sep 2020 15:55:40
User entered 'Day 7'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:55:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-10T18:40:41', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '8054b9d4-cb5c-4095-b8fc-5042bd5428d1' User entered 'None (0)'	System	10 Sep 2020 22:41:08
	System	10 Sep 2020 22:41:08

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:55:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-10T18:40:45', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '8054b9d4-cb5c-4095-b8fc-5042bd5428d1' User entered 'None (0)'	System	10 Sep 2020 22:41:08
	System	10 Sep 2020 22:41:08

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-10T18:40:48', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '8054b9d4-cb5c-4095-b8fc-5042bd5428d1' User entered 'None (0)'	System	10 Sep 2020 22:41:08
	System	10 Sep 2020 22:41:08

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-10T18:40:50', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '8054b9d4-cb5c-4095-b8fc-5042bd5428d1' User entered 'None (0)'	System	10 Sep 2020 22:41:08
	System	10 Sep 2020 22:41:08

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-10T18:40:53', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '8054b9d4-cb5c-4095-b8fc-5042bd5428d1' User entered 'None (0)'	System	10 Sep 2020 22:41:08
	System	10 Sep 2020 22:41:08

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:55:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-10T18:40:56', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '8054b9d4-cb5c-4095-b8fc-5042bd5428d1' User entered 'None (0)'	System	10 Sep 2020 22:41:08
	System	10 Sep 2020 22:41:08

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:55:38

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)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-10T18:41:02', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '8054b9d4-cb5c-4095-b8fc-5042bd5428d1' User entered 'No (N)'	System	10 Sep 2020 22:41:08
	System	10 Sep 2020 22:41:08

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-09-10T18:41:05', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '8054b9d4-cb5c-4095-b8fc-5042bd5428d1' User entered '10 Sep 2020 18:41'	System	10 Sep 2020 22:41:08
	System	10 Sep 2020 22:41:08

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 15:55:40

US3512217

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 15:55:40

US3512217

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:53:45
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	16 Sep 2020 22:21:10
	(b) (4)	

US3512217

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:53:45
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	18 Sep 2020 04:05:23
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Many contacts attempted starting september 12, 2020' (Site from System).	Sheldon Warren (b) (4) (b) (4)	16 Sep 2020 22:21:37
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	16 Sep 2020 22:21:10
User entered '16 Sep 2020'	Sheldon Warren (b) (4) (b) (4)	16 Sep 2020 22:21:10

US3512217

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:53:45
User entered 'Contact Made (CONTACT MADE)'	Sheldon Warren (b) (4)	16 Sep 2020 22:21:10
	(b) (4)	

US3512217

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:53:45
User entered empty.	Sheldon Warren (b) (4) (b) (4)	16 Sep 2020 22:21:10

US3512217

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:53:51
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	16 Sep 2020 22:21:43
	(b) (4)	

US3512217

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'I'	System	16 Sep 2020 22:21:43

US3512217

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:54:58
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	16 Sep 2020 22:28:46
	(b) (4)	

US3512217

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User closed query 'Per source date of contact is 18Sep2020 and not 16Sep2020. Please review and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Oct 2020 18:33:02
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:32:40
Query 'Per source date of contact is 18Sep2020 and not 16Sep2020. Please review and update accordingly.' answered with 'UPDATED' (Site from CRA).	Allison Crain (b) (4)	15 Oct 2020 18:50:07
User entered '18 Sep 2020' reason for change: Data Entry Error	Allison Crain (b) (4)	15 Oct 2020 18:50:01
User opened query 'Per source date of contact is 18Sep2020 and not 16Sep2020. Please review and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	06 Oct 2020 16:54:55
DataPoint Un-verified.	(b) (4), (b) (6)	06 Oct 2020 16:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:54:17
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	06 Oct 2020 02:42:35
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'confirm as is' (Site from System).	Brenda Anderson (b) (4)	02 Oct 2020 16:23:33
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	16 Sep 2020 22:28:46
User entered '16 Sep 2020'	Sheldon Warren (b) (4)	16 Sep 2020 22:28:46

US3512217

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:55:02
User entered 'Contact Made (CONTACT MADE)'	Sheldon Warren (b) (4) (b) (4)	16 Sep 2020 22:28:46

US3512217

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	16 Oct 2020 18:32:40
User entered empty.	Sheldon Warren (b) (4)	16 Sep 2020 22:28:46
	(b) (4)	

US3512217

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:55:07
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	22 Sep 2020 01:03:02
	(b) (4)	

US3512217

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'I'	System	22 Sep 2020 01:03:02

US3512217

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	06 Oct 2020 16:55:24
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	29 Sep 2020 14:33:00

US3512217

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:55:24
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	01 Oct 2020 09:02:28
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'multiple prior attempts' (Site from System).	Sheldon Warren (b) (4) (b) (4)	29 Sep 2020 14:33:16
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	29 Sep 2020 14:33:00
User entered '29 Sep 2020'	Sheldon Warren (b) (4) (b) (4)	29 Sep 2020 14:33:00

US3512217

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	06 Oct 2020 16:55:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Sep 2020 14:33:00
	Sheldon Warren (b) (4)	
	(b) (4)	

US3512217

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:55:24
User entered empty.	Sheldon Warren (b) (4) (b) (4)	29 Sep 2020 14:33:00

US3512217

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:57:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	29 Sep 2020 14:33:24

US3512217

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'I'	System	29 Sep 2020 14:33:24

US3512217

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
		03 Nov 2020 20:19:27
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	02 Oct 2020 17:21:40
	(b) (4)	

US3512217

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 20:19:27
User entered '2 Oct 2020'	Brenda Anderson (b) (4)	02 Oct 2020 17:21:40
	(b) (4)	

US3512217

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[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 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 20:19:27
User entered 'Clinic (Clinic)'	Brenda Anderson (b) (4)	02 Oct 2020 17:21:40
	(b) (4)	

US3512217

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'VISIT2'	System	02 Oct 2020 17:21:40

US3512217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Anderson (b) (4)	02 Oct 2020 17:23:59

US3512217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
		03 Nov 2020 20:20:16
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	02 Oct 2020 17:23:59
	(b) (4)	

US3512217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 20:20:16
User entered '2 Oct 2020'	Brenda Anderson (b) (4)	02 Oct 2020 17:23:59
	(b) (4)	

US3512217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 20:20:16
User entered '11:12'	Brenda Anderson (b) (4)	02 Oct 2020 17:23:59
	(b) (4)	

US3512217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered '2 Oct 2020 11:12'	System	02 Oct 2020 17:23:59

US3512217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
		03 Nov 2020 20:20:16
User entered '97.4' F	Brenda Anderson (b) (4)	02 Oct 2020 17:23:59
	(b) (4)	

US3512217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
		03 Nov 2020 20:20:16
User entered 'Oral (Oral)'	Brenda Anderson (b) (4)	02 Oct 2020 17:23:59
	(b) (4)	

US3512217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 20:20:16
User entered empty.	Brenda Anderson (b) (4)	02 Oct 2020 17:23:59
	(b) (4)	

US3512217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 20:20:16
User entered '63'	Brenda Anderson (b) (4)	02 Oct 2020 17:23:59
	(b) (4)	

US3512217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'bpm'	System	02 Oct 2020 17:23:59

US3512217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
		03 Nov 2020 20:20:16
User entered '12'	Brenda Anderson (b) (4)	02 Oct 2020 17:23:59
	(b) (4)	

US3512217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'breaths/min'	System	02 Oct 2020 17:23:59

US3512217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '114'	Brenda Anderson (b) (4)	02 Oct 2020 17:23:59

US3512217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'mmHg'	System	02 Oct 2020 17:23:59

US3512217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	03 Nov 2020 20:20:16
User entered '69'	Brenda Anderson (b) (4)	02 Oct 2020 17:23:59
	(b) (4)	

US3512217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'mmHg'	System	02 Oct 2020 17:23:59

US3512217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Anderson (b) (4) (b) (4)	02 Oct 2020 17:23:59

US3512217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
		03 Nov 2020 20:20:16
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	02 Oct 2020 17:23:59
	(b) (4)	

US3512217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 20:20:16
User entered '2 Oct 2020'	Brenda Anderson (b) (4)	02 Oct 2020 17:23:59
	(b) (4)	

US3512217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 20:20:16
User entered '12:40'	Brenda Anderson (b) (4)	02 Oct 2020 17:23:59
	(b) (4)	

US3512217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered '2 Oct 2020 12:40'	System	02 Oct 2020 17:23:59

US3512217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
		03 Nov 2020 20:20:16
User entered '99.1' F	Brenda Anderson (b) (4)	02 Oct 2020 17:23:59
	(b) (4)	

US3512217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
		03 Nov 2020 20:20:16
User entered 'Oral (Oral)'	Brenda Anderson (b) (4)	02 Oct 2020 17:23:59
	(b) (4)	

US3512217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Brenda Anderson (b) (4)	02 Oct 2020 17:23:59

US3512217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 20:20:16
User entered '63'	Brenda Anderson (b) (4)	02 Oct 2020 17:23:59
	(b) (4)	

US3512217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'bpm'	System	02 Oct 2020 17:23:59

US3512217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 20:20:16
User entered '12'	Brenda Anderson (b) (4)	02 Oct 2020 17:23:59
	(b) (4)	

US3512217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'breaths/min'	System	02 Oct 2020 17:23:59

US3512217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '123'	Brenda Anderson (b) (4)	02 Oct 2020 17:23:59

US3512217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'mmHg'	System	02 Oct 2020 17:23:59

US3512217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '72'	Brenda Anderson (b) (4)	02 Oct 2020 17:23:59
	(b) (4)	

US3512217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'mmHg'	System	02 Oct 2020 17:23:59

US3512217

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:55:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
		03 Nov 2020 20:20:27
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	02 Oct 2020 17:24:32
	(b) (4)	

US3512217

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:55:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 20:20:27
User entered '2 Oct 2020'	Brenda Anderson (b) (4)	02 Oct 2020 17:24:32
	(b) (4)	

US3512217

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	03 Nov 2020 20:20:37
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	02 Oct 2020 16:21:27
	(b) (4)	

US3512217

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 20:20:37
User entered empty.	Brenda Anderson (b) (4)	02 Oct 2020 16:21:27
	(b) (4)	

US3512217

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

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)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:20:37
User entered empty.	Brenda Anderson (b) (4) (b) (4)	02 Oct 2020 16:21:27

US3512217

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'MRNA-1273 OR PLACEBO'	System	02 Oct 2020 16:21:27

US3512217

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
		03 Nov 2020 20:20:37
User entered '2 Oct 2020'	Brenda Anderson (b) (4)	02 Oct 2020 16:21:27
	(b) (4)	

US3512217

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	03 Nov 2020 20:20:37
User entered '12:08'	Brenda Anderson (b) (4)	02 Oct 2020 16:21:27
	(b) (4)	

US3512217

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered '2 Oct 2020 12:08'	System	02 Oct 2020 16:21:27

US3512217

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	03 Nov 2020 20:20:37
User entered 'Left Arm (LEFT ARM)'	Brenda Anderson (b) (4)	02 Oct 2020 16:21:27
	(b) (4)	

US3512217

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:20:37
User entered 'ONCE'	System	02 Oct 2020 16:21:27

US3512217

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'INTRAMUSCULAR'	System	02 Oct 2020 16:21:27

US3512217

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	03 Nov 2020 20:20:59
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	02 Oct 2020 17:24:59
	(b) (4)	

US3512217

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 02OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 13:04:41
	(b) (4), (b) (6)	03 Nov 2020 20:20:59
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 02OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'Do to lack of supplies at site, unscheduled kit was used for this scheduled visit with monitor approval for all.' (Site from DM).	Allison Crain (b) (4)	23 Oct 2020 16:00:59
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 02OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 15:23:55
User entered '2 Oct 2020'	Brenda Anderson (b) (4)	02 Oct 2020 17:24:59

US3512217

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	03 Nov 2020 20:20:59
User entered '11:27'	Brenda Anderson (b) (4)	02 Oct 2020 17:24:59
	(b) (4)	

US3512217

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered '2 Oct 2020 11:27'	System	02 Oct 2020 17:24:59

US3512217

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 07:55:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:21:08
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 02Oct2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 09:44:53
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 02Oct2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' answered with 'Due to lack of supplies on site, UNSCHEDULED lab kits were used for the Visit 2 Day 29 labs. This was approved by monitor and are not two separate visits.' (Site from DM).	Allison Crain (b) (4) (b) (4)	21 Oct 2020 12:37:43
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 02Oct2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 06:07:37
User entered '2 Oct 2020'	Brenda Anderson (b) (4) (b) (4)	02 Oct 2020 17:25:14

US3512217

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:55:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brenda Anderson (b) (4)	02 Oct 2020 17:25:14

US3512217

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:55:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 20:21:08
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	02 Oct 2020 17:25:14
	(b) (4)	

US3512217

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:55:38

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:21:08
User entered '11:20'	Brenda Anderson (b) (4) (b) (4)	02 Oct 2020 17:25:14

US3512217

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered '2 Oct 2020 11:20'	System	02 Oct 2020 17:25:14

US3512217

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:55:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brenda Anderson (b) (4)	02 Oct 2020 17:25:14

US3512217

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:55:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:21:08
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	02 Oct 2020 17:25:14

US3512217

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:55:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:21:08
User entered empty.	Brenda Anderson (b) (4) (b) (4)	02 Oct 2020 17:25:14

US3512217

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered empty.	System	02 Oct 2020 17:25:14

US3512217

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 20:21:15
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	02 Oct 2020 17:25:33
	(b) (4)	

US3512217

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'I'	System	02 Oct 2020 17:25:33

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	02 Oct 2020 16:21:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-02T12:41:22', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'c616966d-4892-44a7-b25c-b255e6c0035c' User entered 'Yes (Y)'	System	02 Oct 2020 16:42:33
	System	02 Oct 2020 16:42:33

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-02T12:41:59', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'c616966d-4892-44a7-b25c-b255e6c0035c' User entered '97.1'	System	02 Oct 2020 16:42:33
	System	02 Oct 2020 16:42:33

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-02T12:42:26', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'c616966d-4892-44a7-b25c-b255e6c0035c' User entered 'No (N)'	System	02 Oct 2020 16:42:33
	System	02 Oct 2020 16:42:33

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-02T12:42:30', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'c616966d-4892-44a7-b25c-b255e6c0035c' User entered '02 Oct 2020 12:42'	System	02 Oct 2020 16:42:33
	System	02 Oct 2020 16:42:33

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '02 Oct 2020 12:28'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '02 Oct 2020 14:58'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	02 Oct 2020 16:21:27
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-02T18:31:20', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '377b8e68-7fa5-49cb-94b6-a5d170584730' User entered 'Yes (Y)'	System	02 Oct 2020 22:31:45
	System	02 Oct 2020 22:31:45

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-02T18:31:26', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '377b8e68-7fa5-49cb-94b6-a5d170584730' User entered '98.7'	System	02 Oct 2020 22:31:45
	System	02 Oct 2020 22:31:45

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-02T18:31:34', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '377b8e68-7fa5-49cb-94b6-a5d170584730' User entered 'No (N)'	System	02 Oct 2020 22:31:45
	System	02 Oct 2020 22:31:45

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-02T18:31:41', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '377b8e68-7fa5-49cb-94b6-a5d170584730' User entered '02 Oct 2020 18:31'	System	02 Oct 2020 22:31:45
	System	02 Oct 2020 22:31:45

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '02 Oct 2020 15:53'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	02 Oct 2020 16:21:27
User entered 'Day 2'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-03T19:53:11', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '19d0ddc0-21d9-42e9-8337-e630d48f22c6' User entered 'Yes (Y)'	System	03 Oct 2020 23:53:35
	System	03 Oct 2020 23:53:35

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-03T19:53:21', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '19d0ddc0-21d9-42e9-8337-e630d48f22c6' User entered '98.3'	System	03 Oct 2020 23:53:35
	System	03 Oct 2020 23:53:35

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-03T19:53:26', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '19d0ddc0-21d9-42e9-8337-e630d48f22c6' User entered 'No (N)'	System	03 Oct 2020 23:53:35
	System	03 Oct 2020 23:53:35

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-03T19:53:30', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '19d0ddc0-21d9-42e9-8337-e630d48f22c6' User entered '03 Oct 2020 19:53'	System	03 Oct 2020 23:53:35
	System	03 Oct 2020 23:53:35

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	02 Oct 2020 16:21:27
User entered 'Day 3'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-04T20:27:36', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '111aa7fd-f9d6-4441-ad72-f4cdac9170af' User entered 'Yes (Y)'	System	05 Oct 2020 00:27:52
	System	05 Oct 2020 00:27:52

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-04T20:27:43', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '111aa7fd-f9d6-4441-ad72-f4cdac9170af' User entered '98.7'	System	05 Oct 2020 00:27:52
	System	05 Oct 2020 00:27:52

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-04T20:27:46', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '111aa7fd-f9d6-4441-ad72-f4cdac9170af' User entered 'No (N)'	System	05 Oct 2020 00:27:52
	System	05 Oct 2020 00:27:52

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-04T20:27:50', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '111aa7fd-f9d6-4441-ad72-f4cdac9170af' User entered '04 Oct 2020 20:27'	System	05 Oct 2020 00:27:52
	System	05 Oct 2020 00:27:52

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	02 Oct 2020 16:21:27
User entered 'Day 4'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-05T23:29:13', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '46f6b91d-70e5-4314-a6f2-987ad2c8873f' User entered 'Yes (Y)'	System	06 Oct 2020 03:29:34
	System	06 Oct 2020 03:29:34

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-05T23:29:23', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '46f6b91d-70e5-4314-a6f2-987ad2c8873f' User entered '98.6'	System	06 Oct 2020 03:29:34
	System	06 Oct 2020 03:29:34

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-05T23:29:27', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '46f6b91d-70e5-4314-a6f2-987ad2c8873f' User entered 'No (N)'	System	06 Oct 2020 03:29:34
	System	06 Oct 2020 03:29:34

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-05T23:29:29', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '46f6b91d-70e5-4314-a6f2-987ad2c8873f' User entered '05 Oct 2020 23:29'	System	06 Oct 2020 03:29:34
	System	06 Oct 2020 03:29:34

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	02 Oct 2020 16:21:27
User entered 'Day 5'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-06T19:51:15', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '4ef3a718-ca47-487d-9f3a-e05d075211ca' User entered 'Yes (Y)'	System	06 Oct 2020 23:51:44
	System	06 Oct 2020 23:51:44

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-06T19:51:29', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '4ef3a718-ca47-487d-9f3a-e05d075211ca' User entered '98.4'	System	06 Oct 2020 23:51:44
	System	06 Oct 2020 23:51:44

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-06T19:51:38', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '4ef3a718-ca47-487d-9f3a-e05d075211ca' User entered 'No (N)'	System	06 Oct 2020 23:51:44
	System	06 Oct 2020 23:51:44

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-06T19:51:40', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '4ef3a718-ca47-487d-9f3a-e05d075211ca' User entered '06 Oct 2020 19:51'	System	06 Oct 2020 23:51:44
	System	06 Oct 2020 23:51:44

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	02 Oct 2020 16:21:27
User entered 'Day 6'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-07T19:31:35', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '7e411a09-d945-4e10-a6e0-a0d6bd31098d' User entered 'Yes (Y)'	System	07 Oct 2020 23:31:50
	System	07 Oct 2020 23:31:50

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-07T19:31:41', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '7e411a09-d945-4e10-a6e0-a0d6bd31098d' User entered '98.4'	System	07 Oct 2020 23:31:50
	System	07 Oct 2020 23:31:50

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-07T19:31:45', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '7e411a09-d945-4e10-a6e0-a0d6bd31098d' User entered 'No (N)'	System	07 Oct 2020 23:31:50
	System	07 Oct 2020 23:31:50

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-07T19:31:48', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '7e411a09-d945-4e10-a6e0-a0d6bd31098d' User entered '07 Oct 2020 19:31'	System	07 Oct 2020 23:31:50
	System	07 Oct 2020 23:31:50

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	02 Oct 2020 16:21:27
User entered 'Day 7'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-08T22:32:25', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'a28fc4a5-517a-4a72-84bb-f4935751aeaa' User entered 'Yes (Y)'	System	09 Oct 2020 02:32:41
	System	09 Oct 2020 02:32:41

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-08T22:32:31', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'a28fc4a5-517a-4a72-84bb-f4935751aeaa' User entered '98.7'	System	09 Oct 2020 02:32:41
	System	09 Oct 2020 02:32:41

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-08T22:32:35', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'a28fc4a5-517a-4a72-84bb-f4935751aeaa'	System	09 Oct 2020 02:32:41
User entered 'No (N)'	System	09 Oct 2020 02:32:41

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-08T22:32:38', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'a28fc4a5-517a-4a72-84bb-f4935751aeaa' User entered '08 Oct 2020 22:32'	System	09 Oct 2020 02:32:41
	System	09 Oct 2020 02:32:41

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	02 Oct 2020 16:21:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-02T12:42:38', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '3b43a8ac-17a6-45a5-86ea-c4eab0cf3355'	System	02 Oct 2020 16:43:13
User entered 'None (1)'	System	02 Oct 2020 16:43:13

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-02T12:42:46', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '3b43a8ac-17a6-45a5-86ea-c4eab0cf3355'	System	02 Oct 2020 16:43:13
User entered 'No (N)'	System	02 Oct 2020 16:43:13

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-02T12:42:54', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '3b43a8ac-17a6-45a5-86ea-c4eab0cf3355'	System	02 Oct 2020 16:43:13
User entered 'No (N)'	System	02 Oct 2020 16:43:13

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-02T12:43:06', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '3b43a8ac-17a6-45a5-86ea-c4eab0cf3355'	System	02 Oct 2020 16:43:13
User entered 'None (1)'	System	02 Oct 2020 16:43:13

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-02T12:43:09', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '3b43a8ac-17a6-45a5-86ea-c4eab0cf3355'	System	02 Oct 2020 16:43:13
User entered '02 Oct 2020 12:43'	System	02 Oct 2020 16:43:13

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '02 Oct 2020 12:28'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '02 Oct 2020 14:58'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	02 Oct 2020 16:21:27
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-02T18:31:49', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '4619ccdd-9f42-4a52-91e4-20f73a68e476' User entered 'None (1)'	System	02 Oct 2020 22:32:13
	System	02 Oct 2020 22:32:13

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-02T18:32:02', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '4619ccdd-9f42-4a52-91e4-20f73a68e476' User entered 'No (N)'	System	02 Oct 2020 22:32:13
	System	02 Oct 2020 22:32:13

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-02T18:32:05', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '4619ccdd-9f42-4a52-91e4-20f73a68e476' User entered 'No (N)'	System	02 Oct 2020 22:32:13
	System	02 Oct 2020 22:32:13

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-02T18:32:08', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '4619ccdd-9f42-4a52-91e4-20f73a68e476' User entered 'None (1)'	System	02 Oct 2020 22:32:13
	System	02 Oct 2020 22:32:13

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-02T18:32:10', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '4619ccdd-9f42-4a52-91e4-20f73a68e476' User entered '02 Oct 2020 18:32'	System	02 Oct 2020 22:32:13
	System	02 Oct 2020 22:32:13

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '02 Oct 2020 15:53'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	02 Oct 2020 16:21:27
User entered 'Day 2'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:55:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-03T19:53:34', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '082e97ef-09a3-42e9-8408-00732078ec80' User entered 'None (1)'	System	03 Oct 2020 23:53:48
	System	03 Oct 2020 23:53:48

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-03T19:53:38', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '082e97ef-09a3-42e9-8408-00732078ec80' User entered 'No (N)'	System	03 Oct 2020 23:53:48
	System	03 Oct 2020 23:53:48

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-03T19:53:41', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '082e97ef-09a3-42e9-8408-00732078ec80' User entered 'No (N)'	System	03 Oct 2020 23:53:48
	System	03 Oct 2020 23:53:48

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:55:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-03T19:53:43', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '082e97ef-09a3-42e9-8408-00732078ec80' User entered 'None (1)'	System	03 Oct 2020 23:53:48
	System	03 Oct 2020 23:53:48

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-03T19:53:46', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '082e97ef-09a3-42e9-8408-00732078ec80' User entered '03 Oct 2020 19:53'	System	03 Oct 2020 23:53:48
	System	03 Oct 2020 23:53:48

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	02 Oct 2020 16:21:27
User entered 'Day 3'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:55:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-04T20:27:55', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '66a7fc65-c63f-43ab-acc-498486c166e7' User entered 'None (1)'	System	05 Oct 2020 00:28:08
	System	05 Oct 2020 00:28:08

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-04T20:27:58', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '66a7fc65-c63f-43ab-accc-498486c166e7' User entered 'No (N)'	System	05 Oct 2020 00:28:08
	System	05 Oct 2020 00:28:08

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-04T20:28:01', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '66a7fc65-c63f-43ab-accc-498486c166e7' User entered 'No (N)'	System	05 Oct 2020 00:28:08
	System	05 Oct 2020 00:28:08

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:55:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-04T20:28:03', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '66a7fc65-c63f-43ab-acc-498486c166e7' User entered 'None (1)'	System	05 Oct 2020 00:28:08
	System	05 Oct 2020 00:28:08

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-04T20:28:05', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '66a7fc65-c63f-43ab-accc-498486c166e7' User entered '04 Oct 2020 20:28'	System	05 Oct 2020 00:28:08
	System	05 Oct 2020 00:28:08

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	02 Oct 2020 16:21:27
User entered 'Day 4'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:55:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-05T23:29:34', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '18365596-e501-455e-969a-b99b884df7a1' User entered 'None (1)'	System	06 Oct 2020 03:29:49
	System	06 Oct 2020 03:29:49

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-05T23:29:40', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '18365596-e501-455e-969a-b99b884df7a1' User entered 'No (N)'	System	06 Oct 2020 03:29:49
	System	06 Oct 2020 03:29:49

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-05T23:29:42', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '18365596-e501-455e-969a-b99b884df7a1' User entered 'No (N)'	System	06 Oct 2020 03:29:49
	System	06 Oct 2020 03:29:49

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:55:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-05T23:29:44', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '18365596-e501-455e-969a-b99b884df7a1' User entered 'None (1)'	System	06 Oct 2020 03:29:49
	System	06 Oct 2020 03:29:49

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-05T23:29:47', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '18365596-e501-455e-969a-b99b884df7a1' User entered '05 Oct 2020 23:29'	System	06 Oct 2020 03:29:49
	System	06 Oct 2020 03:29:49

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	02 Oct 2020 16:21:27
User entered 'Day 5'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:55:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-06T19:51:45', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '03d814bf-0b8c-4cc6-8e26-aad6bc08d264' User entered 'None (1)'	System	06 Oct 2020 23:51:59
	System	06 Oct 2020 23:51:59

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-06T19:51:50', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '03d814bf-0b8c-4cc6-8e26-aad6bc08d264' User entered 'No (N)'	System	06 Oct 2020 23:51:59
	System	06 Oct 2020 23:51:59

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-06T19:51:53', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '03d814bf-0b8c-4cc6-8e26-aad6bc08d264' User entered 'No (N)'	System	06 Oct 2020 23:51:59
	System	06 Oct 2020 23:51:59

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:55:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-06T19:51:55', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '03d814bf-0b8c-4cc6-8e26-aad6bc08d264' User entered 'None (1)'	System	06 Oct 2020 23:51:59
	System	06 Oct 2020 23:51:59

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-06T19:51:57', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '03d814bf-0b8c-4cc6-8e26-aad6bc08d264' User entered '06 Oct 2020 19:51'	System	06 Oct 2020 23:51:59
	System	06 Oct 2020 23:51:59

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	02 Oct 2020 16:21:27
User entered 'Day 6'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:55:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-07T19:31:52', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '2262826a-e7e1-4bac-bd7b-9133121a12d4' User entered 'None (1)'	System	07 Oct 2020 23:32:07
	System	07 Oct 2020 23:32:07

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-07T19:31:56', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '2262826a-e7e1-4bac-bd7b-9133121a12d4' User entered 'No (N)'	System	07 Oct 2020 23:32:07
	System	07 Oct 2020 23:32:07

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-07T19:31:59', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '2262826a-e7e1-4bac-bd7b-9133121a12d4' User entered 'No (N)'	System	07 Oct 2020 23:32:07
	System	07 Oct 2020 23:32:07

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:55:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-07T19:32:01', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '2262826a-e7e1-4bac-bd7b-9133121a12d4' User entered 'None (1)'	System	07 Oct 2020 23:32:07
	System	07 Oct 2020 23:32:07

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-07T19:32:05', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '2262826a-e7e1-4bac-bd7b-9133121a12d4' User entered '07 Oct 2020 19:32'	System	07 Oct 2020 23:32:07
	System	07 Oct 2020 23:32:07

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	02 Oct 2020 16:21:27
User entered 'Day 7'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:55:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-08T22:32:44', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '0210ff1a-b227-40e3-a4f6-f5014df03835'	System	09 Oct 2020 02:33:01
User entered 'None (1)'	System	09 Oct 2020 02:33:01

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-08T22:32:49', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '0210ff1a-b227-40e3-a4f6-f5014df03835' User entered 'No (N)'	System	09 Oct 2020 02:33:01
	System	09 Oct 2020 02:33:01

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-08T22:32:51', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '0210ff1a-b227-40e3-a4f6-f5014df03835' User entered 'No (N)'	System	09 Oct 2020 02:33:01
	System	09 Oct 2020 02:33:01

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:55:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-08T22:32:53', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '0210ff1a-b227-40e3-a4f6-f5014df03835'	System	09 Oct 2020 02:33:01
User entered 'None (1)'	System	09 Oct 2020 02:33:01

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-08T22:32:57', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '0210ff1a-b227-40e3-a4f6-f5014df03835' User entered '08 Oct 2020 22:32'	System	09 Oct 2020 02:33:01
	System	09 Oct 2020 02:33:01

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	02 Oct 2020 16:21:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-02T12:43:16', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'f165b2c6-dbc2-4d46-b08d-fee06dd834ca' User entered 'None (0)'	System	02 Oct 2020 16:44:05
	System	02 Oct 2020 16:44:05

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-02T12:43:19', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'f165b2c6-dbc2-4d46-b08d-fee06dd834ca' User entered 'None (0)'	System	02 Oct 2020 16:44:05
	System	02 Oct 2020 16:44:05

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-02T12:43:25', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'f165b2c6-dbc2-4d46-b08d-fee06dd834ca' User entered 'None (0)'	System	02 Oct 2020 16:44:05
	System	02 Oct 2020 16:44:05

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-02T12:43:33', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'f165b2c6-dbc2-4d46-b08d-fee06dd834ca' User entered 'None (0)'	System	02 Oct 2020 16:44:05
	System	02 Oct 2020 16:44:05

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-02T12:43:38', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'f165b2c6-dbc2-4d46-b08d-fee06dd834ca' User entered 'None (0)'	System	02 Oct 2020 16:44:05
	System	02 Oct 2020 16:44:05

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-02T12:43:41', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'f165b2c6-dbc2-4d46-b08d-fee06dd834ca' User entered 'None (0)'	System	02 Oct 2020 16:44:05
	System	02 Oct 2020 16:44:05

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

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)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-02T12:43:51', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'f165b2c6-dbc2-4d46-b08d-fee06dd834ca' User entered 'No (N)'	System	02 Oct 2020 16:44:05
	System	02 Oct 2020 16:44:05

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-02T12:44:01', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'f165b2c6-dbc2-4d46-b08d-fee06dd834ca' User entered '02 Oct 2020 12:44'	System	02 Oct 2020 16:44:05
	System	02 Oct 2020 16:44:05

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '02 Oct 2020 12:28'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '02 Oct 2020 14:58'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	02 Oct 2020 16:21:27
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-02T18:32:16', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '96a94207-3c0d-403d-ae6e-e71a548d3445' User entered 'None (0)'	System	02 Oct 2020 22:32:45
	System	02 Oct 2020 22:32:45

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-02T18:32:18', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '96a94207-3c0d-403d-ae6e-e71a548d3445' User entered 'None (0)'	System	02 Oct 2020 22:32:45
	System	02 Oct 2020 22:32:45

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-02T18:32:23', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '96a94207-3c0d-403d-ae6e-e71a548d3445' User entered 'None (0)'	System	02 Oct 2020 22:32:45
	System	02 Oct 2020 22:32:45

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-02T18:32:27', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '96a94207-3c0d-403d-ae6e-e71a548d3445' User entered 'None (0)'	System	02 Oct 2020 22:32:45
	System	02 Oct 2020 22:32:45

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-02T18:32:31', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '96a94207-3c0d-403d-ae6e-e71a548d3445' User entered 'None (0)'	System	02 Oct 2020 22:32:45
	System	02 Oct 2020 22:32:45

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-02T18:32:33', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '96a94207-3c0d-403d-ae6e-e71a548d3445' User entered 'None (0)'	System	02 Oct 2020 22:32:45
	System	02 Oct 2020 22:32:45

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

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)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-02T18:32:40', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '96a94207-3c0d-403d-ae6e-e71a548d3445' User entered 'No (N)'	System	02 Oct 2020 22:32:45
	System	02 Oct 2020 22:32:45

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-02T18:32:42', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '96a94207-3c0d-403d-ae6e-e71a548d3445' User entered '02 Oct 2020 18:32'	System	02 Oct 2020 22:32:45
	System	02 Oct 2020 22:32:45

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '02 Oct 2020 15:53'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	02 Oct 2020 16:21:27
User entered 'Day 2'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:55:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-03T19:53:51', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '504e95b2-646c-4af4-8132-776952a99b7a' User entered 'None (0)'	System	03 Oct 2020 23:54:12
	System	03 Oct 2020 23:54:12

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:55:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-03T19:53:53', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '504e95b2-646c-4af4-8132-776952a99b7a' User entered 'None (0)'	System	03 Oct 2020 23:54:12
	System	03 Oct 2020 23:54:12

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-03T19:53:55', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '504e95b2-646c-4af4-8132-776952a99b7a' User entered 'None (0)'	System	03 Oct 2020 23:54:12
	System	03 Oct 2020 23:54:12

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-03T19:53:57', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '504e95b2-646c-4af4-8132-776952a99b7a' User entered 'None (0)'	System	03 Oct 2020 23:54:12
	System	03 Oct 2020 23:54:12

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-03T19:53:59', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '504e95b2-646c-4af4-8132-776952a99b7a' User entered 'None (0)'	System	03 Oct 2020 23:54:12
	System	03 Oct 2020 23:54:12

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:55:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-03T19:54:02', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '504e95b2-646c-4af4-8132-776952a99b7a' User entered 'None (0)'	System	03 Oct 2020 23:54:12
	System	03 Oct 2020 23:54:12

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:55:38

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)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-03T19:54:08', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '504e95b2-646c-4af4-8132-776952a99b7a' User entered 'No (N)'	System	03 Oct 2020 23:54:12
	System	03 Oct 2020 23:54:12

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-03T19:54:10', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '504e95b2-646c-4af4-8132-776952a99b7a' User entered '03 Oct 2020 19:54'	System	03 Oct 2020 23:54:12
	System	03 Oct 2020 23:54:12

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	02 Oct 2020 16:21:27
User entered 'Day 3'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:55:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-04T20:28:09', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '0708c860-5f3a-43f5-bd8b-20b2e79c20b2' User entered 'None (0)'	System	05 Oct 2020 00:28:30
	System	05 Oct 2020 00:28:30

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:55:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-04T20:28:12', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '0708c860-5f3a-43f5-bd8b-20b2e79c20b2' User entered 'None (0)'	System	05 Oct 2020 00:28:30
	System	05 Oct 2020 00:28:30

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-04T20:28:14', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '0708c860-5f3a-43f5-bd8b-20b2e79c20b2' User entered 'None (0)'	System	05 Oct 2020 00:28:30
	System	05 Oct 2020 00:28:30

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-04T20:28:16', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '0708c860-5f3a-43f5-bd8b-20b2e79c20b2' User entered 'None (0)'	System	05 Oct 2020 00:28:30
	System	05 Oct 2020 00:28:30

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-04T20:28:18', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '0708c860-5f3a-43f5-bd8b-20b2e79c20b2' User entered 'None (0)'	System	05 Oct 2020 00:28:30
	System	05 Oct 2020 00:28:30

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:55:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-04T20:28:20', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '0708c860-5f3a-43f5-bd8b-20b2e79c20b2' User entered 'None (0)'	System	05 Oct 2020 00:28:30
	System	05 Oct 2020 00:28:30

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:55:38

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)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-04T20:28:26', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '0708c860-5f3a-43f5-bd8b-20b2e79c20b2' User entered 'No (N)'	System	05 Oct 2020 00:28:30
	System	05 Oct 2020 00:28:30

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-04T20:28:28', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '0708c860-5f3a-43f5-bd8b-20b2e79c20b2' User entered '04 Oct 2020 20:28'	System	05 Oct 2020 00:28:30
	System	05 Oct 2020 00:28:30

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	02 Oct 2020 16:21:27
User entered 'Day 4'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:55:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-05T23:29:51', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '3f0b16e6-fda8-4c47-b6cf-aa6d91774ee4' User entered 'None (0)'	System	06 Oct 2020 03:30:12
	System	06 Oct 2020 03:30:12

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:55:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-05T23:29:53', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '3f0b16e6-fda8-4c47-b6cf-aa6d91774ee4' User entered 'None (0)'	System	06 Oct 2020 03:30:12
	System	06 Oct 2020 03:30:12

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-05T23:29:55', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '3f0b16e6-fda8-4c47-b6cf-aa6d91774ee4' User entered 'None (0)'	System	06 Oct 2020 03:30:12
	System	06 Oct 2020 03:30:12

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-05T23:29:58', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '3f0b16e6-fda8-4c47-b6cf-aa6d91774ee4' User entered 'None (0)'	System	06 Oct 2020 03:30:12
	System	06 Oct 2020 03:30:12

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-05T23:30:00', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '3f0b16e6-fda8-4c47-b6cf-aa6d91774ee4' User entered 'None (0)'	System	06 Oct 2020 03:30:12
	System	06 Oct 2020 03:30:12

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:55:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-05T23:30:02', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '3f0b16e6-fda8-4c47-b6cf-aa6d91774ee4' User entered 'None (0)'	System	06 Oct 2020 03:30:12
	System	06 Oct 2020 03:30:12

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:55:38

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)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-05T23:30:07', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '3f0b16e6-fda8-4c47-b6cf-aa6d91774ee4' User entered 'No (N)'	System	06 Oct 2020 03:30:12
	System	06 Oct 2020 03:30:12

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-05T23:30:10', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '3f0b16e6-fda8-4c47-b6cf-aa6d91774ee4' User entered '05 Oct 2020 23:30'	System	06 Oct 2020 03:30:12
	System	06 Oct 2020 03:30:12

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	02 Oct 2020 16:21:27
User entered 'Day 5'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:55:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-06T19:52:03', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'a9b1e38f-1e96-4574-95d7-f5cc95cfb95f' User entered 'None (0)'	System	06 Oct 2020 23:52:27
	System	06 Oct 2020 23:52:27

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:55:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-06T19:52:05', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'a9b1e38f-1e96-4574-95d7-f5cc95cfb95f' User entered 'None (0)'	System	06 Oct 2020 23:52:27
	System	06 Oct 2020 23:52:27

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-06T19:52:09', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'a9b1e38f-1e96-4574-95d7-f5cc95cfb95f' User entered 'None (0)'	System	06 Oct 2020 23:52:27
	System	06 Oct 2020 23:52:27

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-06T19:52:12', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'a9b1e38f-1e96-4574-95d7-f5cc95cfb95f' User entered 'None (0)'	System	06 Oct 2020 23:52:27
	System	06 Oct 2020 23:52:27

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-06T19:52:14', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'a9b1e38f-1e96-4574-95d7-f5cc95cfb95f' User entered 'None (0)'	System	06 Oct 2020 23:52:27
	System	06 Oct 2020 23:52:27

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:55:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-06T19:52:17', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'a9b1e38f-1e96-4574-95d7-f5cc95cfb95f' User entered 'None (0)'	System	06 Oct 2020 23:52:27
	System	06 Oct 2020 23:52:27

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:55:38

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)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-06T19:52:22', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'a9b1e38f-1e96-4574-95d7-f5cc95cfb95f' User entered 'No (N)'	System	06 Oct 2020 23:52:27
	System	06 Oct 2020 23:52:27

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-06T19:52:25', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'a9b1e38f-1e96-4574-95d7-f5cc95cfb95f' User entered '06 Oct 2020 19:52'	System	06 Oct 2020 23:52:27
	System	06 Oct 2020 23:52:27

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	02 Oct 2020 16:21:27
User entered 'Day 6'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:55:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-07T19:32:09', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '19750203-c7b2-4823-9aeb-ead2b908f19e' User entered 'None (0)'	System	07 Oct 2020 23:32:30
	System	07 Oct 2020 23:32:30

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:55:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-07T19:32:11', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '19750203-c7b2-4823-9aeb-ead2b908f19e' User entered 'None (0)'	System	07 Oct 2020 23:32:30
	System	07 Oct 2020 23:32:30

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-07T19:32:12', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '19750203-c7b2-4823-9aeb-ead2b908f19e' User entered 'None (0)'	System	07 Oct 2020 23:32:30
	System	07 Oct 2020 23:32:30

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-07T19:32:15', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '19750203-c7b2-4823-9aeb-ead2b908f19e' User entered 'None (0)'	System	07 Oct 2020 23:32:30
	System	07 Oct 2020 23:32:30

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-07T19:32:17', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '19750203-c7b2-4823-9aeb-ead2b908f19e' User entered 'None (0)'	System	07 Oct 2020 23:32:30
	System	07 Oct 2020 23:32:30

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:55:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-07T19:32:19', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '19750203-c7b2-4823-9aeb-ead2b908f19e' User entered 'None (0)'	System	07 Oct 2020 23:32:30
	System	07 Oct 2020 23:32:30

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:55:38

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)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-07T19:32:23', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '19750203-c7b2-4823-9aeb-ead2b908f19e' User entered 'No (N)'	System	07 Oct 2020 23:32:30
	System	07 Oct 2020 23:32:30

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-07T19:32:26', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '19750203-c7b2-4823-9aeb-ead2b908f19e' User entered '07 Oct 2020 19:32'	System	07 Oct 2020 23:32:30
	System	07 Oct 2020 23:32:30

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	02 Oct 2020 16:21:27
User entered 'Day 7'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:55:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-08T22:33:01', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'f1f18c06-1cd5-46d0-8bda-660a52622be4' User entered 'None (0)'	System	09 Oct 2020 02:33:22
	System	09 Oct 2020 02:33:22

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:55:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-08T22:33:03', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'f1f18c06-1cd5-46d0-8bda-660a52622be4' User entered 'None (0)'	System	09 Oct 2020 02:33:22
	System	09 Oct 2020 02:33:22

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-08T22:33:05', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'f1f18c06-1cd5-46d0-8bda-660a52622be4' User entered 'None (0)'	System	09 Oct 2020 02:33:22
	System	09 Oct 2020 02:33:22

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-08T22:33:07', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'f1f18c06-1cd5-46d0-8bda-660a52622be4' User entered 'None (0)'	System	09 Oct 2020 02:33:22
	System	09 Oct 2020 02:33:22

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-08T22:33:09', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'f1f18c06-1cd5-46d0-8bda-660a52622be4' User entered 'None (0)'	System	09 Oct 2020 02:33:22
	System	09 Oct 2020 02:33:22

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:55:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-08T22:33:12', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'f1f18c06-1cd5-46d0-8bda-660a52622be4' User entered 'None (0)'	System	09 Oct 2020 02:33:22
	System	09 Oct 2020 02:33:22

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:55:38

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)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-08T22:33:14', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'f1f18c06-1cd5-46d0-8bda-660a52622be4' User entered 'No (N)'	System	09 Oct 2020 02:33:22
	System	09 Oct 2020 02:33:22

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-10-08T22:33:18', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'f1f18c06-1cd5-46d0-8bda-660a52622be4' User entered '08 Oct 2020 22:33'	System	09 Oct 2020 02:33:22
	System	09 Oct 2020 02:33:22

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 16:21:27

US3512217

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 16:21:27

US3512217

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 20:22:32
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	13 Oct 2020 00:54:10
	(b) (4)	

US3512217

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 20:22:32
User entered '12 Oct 2020'	Sheldon Warren (b) (4)	13 Oct 2020 00:54:10
	(b) (4)	

US3512217

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:22:32
User entered 'Contact Made (CONTACT MADE)'	Sheldon Warren (b) (4) (b) (4)	13 Oct 2020 00:54:10

US3512217

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:22:32
User entered empty.	Sheldon Warren (b) (4) (b) (4)	13 Oct 2020 00:54:10

US3512217

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 20:22:37
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	13 Oct 2020 00:54:16
	(b) (4)	

US3512217

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'I'	System	13 Oct 2020 00:54:16

US3512217

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 20:21:34
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	23 Oct 2020 14:30:37
	(b) (4)	

US3512217

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 20:21:34
User entered '16 Oct 2020'	Sheldon Warren (b) (4)	23 Oct 2020 14:30:37
	(b) (4)	

US3512217

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:21:34
User entered 'Contact Made (CONTACT MADE)'	Sheldon Warren (b) (4) (b) (4)	23 Oct 2020 14:30:37

US3512217

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:21:34
User entered empty.	Sheldon Warren (b) (4) (b) (4)	23 Oct 2020 14:30:37

US3512217

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 20:22:23
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	23 Oct 2020 14:30:46
	(b) (4)	

US3512217

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'I'	System	23 Oct 2020 14:30:46

US3512217

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 20:23:37
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	23 Oct 2020 14:30:58
	(b) (4)	

US3512217

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 20:23:37
User entered '23 Oct 2020'	Sheldon Warren (b) (4)	23 Oct 2020 14:30:58
	(b) (4)	

US3512217

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 20:23:37
User entered 'Contact Made (CONTACT MADE)'	Sheldon Warren (b) (4)	23 Oct 2020 14:30:58
	(b) (4)	

US3512217

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:23:37
User entered empty.	Sheldon Warren (b) (4) (b) (4)	23 Oct 2020 14:30:58

US3512217

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 30Oct2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:21:49
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 30Oct2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'added' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	20 Nov 2020 16:53:26
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 30Oct2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 13:18:48
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:23:42
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	23 Oct 2020 14:31:04

US3512217

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'I'	System	23 Oct 2020 14:31:04

US3512217

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	14 Dec 2020 15:52:14
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	20 Nov 2020 16:53:37
	(b) (4)	

US3512217

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '30 Oct 2020'	Brenda Anderson (b) (4)	20 Nov 2020 16:53:37
	(b) (4)	

US3512217

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[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 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	14 Dec 2020 15:52:14
User entered 'Clinic (Clinic)'	Brenda Anderson (b) (4)	20 Nov 2020 16:53:37
	(b) (4)	

US3512217

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'VISIT3'	System	20 Nov 2020 16:53:37

US3512217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	14 Dec 2020 15:52:24
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	20 Nov 2020 16:54:44
	(b) (4)	

US3512217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
		14 Dec 2020 15:52:24
User entered '30 Oct 2020'	Brenda Anderson (b) (4)	20 Nov 2020 16:54:44
	(b) (4)	

US3512217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	14 Dec 2020 15:52:24
User entered '10:30'	Brenda Anderson (b) (4)	20 Nov 2020 16:54:44
	(b) (4)	

US3512217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered '30 Oct 2020 10:30'	System	20 Nov 2020 16:54:44

US3512217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	14 Dec 2020 15:52:24
User entered '97.0' F	Brenda Anderson (b) (4)	20 Nov 2020 16:54:44
	(b) (4)	

US3512217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	14 Dec 2020 15:52:24
User entered 'Oral (Oral)'	Brenda Anderson (b) (4)	20 Nov 2020 16:54:44
	(b) (4)	

US3512217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Brenda Anderson (b) (4)	20 Nov 2020 16:54:44
	(b) (4)	

US3512217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
		14 Dec 2020 15:52:24
User entered '70'	Brenda Anderson (b) (4)	20 Nov 2020 16:54:44
	(b) (4)	

US3512217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'bpm'	System	20 Nov 2020 16:54:44

US3512217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	14 Dec 2020 15:52:24
User entered '18'	Brenda Anderson (b) (4)	20 Nov 2020 16:54:44
	(b) (4)	

US3512217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'breaths/min'	System	20 Nov 2020 16:54:44

US3512217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	14 Dec 2020 15:52:24
User entered '122'	Brenda Anderson (b) (4)	20 Nov 2020 16:54:44
	(b) (4)	

US3512217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'mmHg'	System	20 Nov 2020 16:54:44

US3512217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	14 Dec 2020 15:52:24
User entered '64'	Brenda Anderson (b) (4)	20 Nov 2020 16:54:44
	(b) (4)	

US3512217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'mmHg'	System	20 Nov 2020 16:54:44

US3512217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39

US3512217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39

US3512217

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:55:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	14 Dec 2020 15:52:31
User entered 'No (N)'	Brenda Anderson (b) (4)	20 Nov 2020 16:54:58
	(b) (4)	

US3512217

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:55:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Brenda Anderson (b) (4)	20 Nov 2020 16:54:58
	(b) (4)	

US3512217

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	14 Dec 2020 15:52:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	20 Nov 2020 16:55:29
	(b) (4)	

US3512217

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '30 Oct 2020'	Brenda Anderson (b) (4)	20 Nov 2020 16:55:29
	(b) (4)	

US3512217

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 15:52:40
User entered '10:39'	Brenda Anderson (b) (4) (b) (4)	20 Nov 2020 16:55:29

US3512217

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered '30 Oct 2020 10:39'	System	20 Nov 2020 16:55:29

US3512217

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	14 Dec 2020 15:52:45
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	20 Nov 2020 16:55:35
	(b) (4)	

US3512217

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'I'	System	20 Nov 2020 16:55:35

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	04 Sep 2020 15:55:40
User entered 'Day 64'	System	04 Sep 2020 15:55:40

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-11-06T17:13:29', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'a8b2261d-945a-408d-bdd4-28daeb09546c' User entered 'No (N)'	System	06 Nov 2020 22:13:52
	System	06 Nov 2020 22:13:52

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-11-06T17:13:36', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'a8b2261d-945a-408d-bdd4-28daeb09546c' User entered 'No (N)'	System	06 Nov 2020 22:13:52
	System	06 Nov 2020 22:13:52

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-11-06T17:13:48', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'a8b2261d-945a-408d-bdd4-28daeb09546c' User entered '06 Nov 2020 17:13:48'	System	06 Nov 2020 22:13:52
	System	06 Nov 2020 22:13:52

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	04 Sep 2020 15:55:40
User entered '04 Nov 2020 00:01'	System	04 Sep 2020 15:55:40

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	04 Sep 2020 15:55:40
User entered '08 Nov 2020 23:59'	System	04 Sep 2020 15:55:40

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	04 Sep 2020 15:55:40
User entered 'Day 71'	System	04 Sep 2020 15:55:40

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-11-14T00:20:40', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'db22be5a-4375-446b-9ea6-465a93a205e0' User entered 'No (N)'	System	14 Nov 2020 05:21:08
	System	14 Nov 2020 05:21:08

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-11-14T00:20:58', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'db22be5a-4375-446b-9ea6-465a93a205e0' User entered 'No (N)'	System	14 Nov 2020 05:21:08
	System	14 Nov 2020 05:21:08

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-11-14T00:21:05', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'db22be5a-4375-446b-9ea6-465a93a205e0' User entered '14 Nov 2020 00:21:05'	System	14 Nov 2020 05:21:08
	System	14 Nov 2020 05:21:08

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	04 Sep 2020 15:55:40
User entered '11 Nov 2020 00:01'	System	04 Sep 2020 15:55:40

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:49:16
Data entry locked.	System	04 Sep 2020 15:55:40
User entered '15 Nov 2020 23:59'	System	04 Sep 2020 15:55:40

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:43:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:49:31
Data entry locked.	System	04 Sep 2020 15:55:40
User entered 'Day 78'	System	04 Sep 2020 15:55:40

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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 14:43:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:49:31

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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 14:43:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:49:31

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Please 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 14:43:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:49:31

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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 14:43:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:49:31

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:43:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:49:31

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:43:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:49:31

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:43:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:49:31

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:43:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:49:31

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:43:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:49:31

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:43:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:49:31

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:43:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:49:31

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:43:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:49:31

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:43:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:49:31

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:43:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:49:31

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:43:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:49:31

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:43:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:49:31

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:43:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:49:31

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:43:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:49:31

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:43:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:49:31

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:43:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:49:31

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:43:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:49:31

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Please 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 14:43:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:49:31

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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 14:43:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:49:31

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Please 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 14:43:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:49:31

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:43:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:49:31

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:43:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:49:31
Data entry locked.	System	04 Sep 2020 15:55:40
User entered '18 Nov 2020 00:01'	System	04 Sep 2020 15:55:40

US3512217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:43:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:49:31
Data entry locked.	System	04 Sep 2020 15:55:40
User entered '22 Nov 2020 23:59'	System	04 Sep 2020 15:55:40

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-12-03T16:55:56', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '12178b83-aa92-4b12-9de3-544a0e8a0ca8' User entered 'No (N)'	System	03 Dec 2020 21:56:15
	System	03 Dec 2020 21:56:15

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-12-03T16:56:08', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '12178b83-aa92-4b12-9de3-544a0e8a0ca8' User entered 'No (N)'	System	03 Dec 2020 21:56:15
	System	03 Dec 2020 21:56:15

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-12-03T16:56:13', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '12178b83-aa92-4b12-9de3-544a0e8a0ca8' User entered '03 Dec 2020 16:56:13'	System	03 Dec 2020 21:56:15
	System	03 Dec 2020 21:56:15

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-12-09T14:44:40', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '01b72e92-7dac-4c30-a6d5-2b32494c92ba' User entered 'No (N)'	System	09 Dec 2020 19:44:49
	System	09 Dec 2020 19:44:49

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-12-09T14:44:42', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '01b72e92-7dac-4c30-a6d5-2b32494c92ba' User entered 'No (N)'	System	09 Dec 2020 19:44:49
	System	09 Dec 2020 19:44:49

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-12-09T14:44:47', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '01b72e92-7dac-4c30-a6d5-2b32494c92ba' User entered '09 Dec 2020 14:44:47'	System	09 Dec 2020 19:44:49
	System	09 Dec 2020 19:44:49

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-12-13T14:10:18', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '42902a0d-b72a-4ea7-aba3-8375fbdf20b3' User entered 'No (N)'	System	13 Dec 2020 19:10:44
	System	13 Dec 2020 19:10:44

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-12-13T14:10:28', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '42902a0d-b72a-4ea7-aba3-8375fbdf20b3' User entered 'No (N)'	System	13 Dec 2020 19:10:44

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-12-13T14:10:41', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '42902a0d-b72a-4ea7-aba3-8375fbdf20b3' User entered '13 Dec 2020 14:10:41'	System	13 Dec 2020 19:10:44
	System	13 Dec 2020 19:10:44

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-12-21T09:50:11', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'c32a74c6-ab07-4365-b78a-ca9ec0cdf47d' User entered 'No (N)'	System	21 Dec 2020 14:50:47
	System	21 Dec 2020 14:50:47

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-12-21T09:50:23', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'c32a74c6-ab07-4365-b78a-ca9ec0cdf47d' User entered 'No (N)'	System	21 Dec 2020 14:50:47

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-12-21T09:50:27', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'c32a74c6-ab07-4365-b78a-ca9ec0cdf47d' User entered '21 Dec 2020 09:50:27'	System	21 Dec 2020 14:50:47
	System	21 Dec 2020 14:50:47

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-12-28T23:15:05', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '08d84d16-c80d-49d6-bfe4-b55ff6510aad' User entered 'No (N)'	System	29 Dec 2020 04:15:16
	System	29 Dec 2020 04:15:16

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-12-28T23:15:08', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '08d84d16-c80d-49d6-bfe4-b55ff6510aad' User entered 'No (N)'	System	29 Dec 2020 04:15:16
	System	29 Dec 2020 04:15:16

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2020-12-28T23:15:13', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '08d84d16-c80d-49d6-bfe4-b55ff6510aad' User entered '28 Dec 2020 23:15:13'	System	29 Dec 2020 04:15:16
	System	29 Dec 2020 04:15:16

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-01-03T23:03:29', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '0e2f2b1a-f470-44c4-84b8-bd58c881be97'	System	04 Jan 2021 04:06:15
User entered 'Yes (Y)'	System	04 Jan 2021 04:06:15

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-01-03T23:03:49', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '0e2f2b1a-f470-44c4-84b8-bd58c881be97'	System	04 Jan 2021 04:06:15
User entered 'No (N)'	System	04 Jan 2021 04:06:15

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-01-03T23:04:01', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '0e2f2b1a-f470-44c4-84b8-bd58c881be97'	System	04 Jan 2021 04:06:15
User entered 'No (N)'	System	04 Jan 2021 04:06:15

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-01-03T23:05:23', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '0e2f2b1a-f470-44c4-84b8-bd58c881be97'	System	04 Jan 2021 04:06:15
User entered 'Yes (Y)'	System	04 Jan 2021 04:06:15

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Please 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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-01-03T23:05:54', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '0e2f2b1a-f470-44c4-84b8-bd58c881be97'	System	04 Jan 2021 04:06:15
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Jan 2021 04:06:15

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-01-03T23:06:06', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '0e2f2b1a-f470-44c4-84b8-bd58c881be97' User entered '03 Jan 2021 23:06:06'	System	04 Jan 2021 04:06:15
	System	04 Jan 2021 04:06:15

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-01-11T18:05:33', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '282cc50a-27c3-43c5-bd4a-ea7b2619b1ad' User entered 'No (N)'	System	11 Jan 2021 23:05:43
	System	11 Jan 2021 23:05:43

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-01-11T18:05:36', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '282cc50a-27c3-43c5-bd4a-ea7b2619b1ad' User entered 'No (N)'	System	11 Jan 2021 23:05:43
	System	11 Jan 2021 23:05:43

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-01-11T18:05:39', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '282cc50a-27c3-43c5-bd4a-ea7b2619b1ad' User entered '11 Jan 2021 18:05:39'	System	11 Jan 2021 23:05:43
	System	11 Jan 2021 23:05:43

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-01-21T16:11:02', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '51caacc0-46b7-4bc5-996f-67b2d918f99e' User entered 'No (N)'	System	21 Jan 2021 21:11:12
	System	21 Jan 2021 21:11:12

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-01-21T16:11:04', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '51caacc0-46b7-4bc5-996f-67b2d918f99e' User entered 'No (N)'	System	21 Jan 2021 21:11:12

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-01-21T16:11:07', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '51caacc0-46b7-4bc5-996f-67b2d918f99e' User entered '21 Jan 2021 16:11:07'	System	21 Jan 2021 21:11:12
	System	21 Jan 2021 21:11:12

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-01-28T19:17:59', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '5b8eb512-6066-4444-a6c1-2f69120569d6' User entered 'No (N)'	System	29 Jan 2021 00:18:12
	System	29 Jan 2021 00:18:12

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-01-28T19:18:01', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '5b8eb512-6066-4444-a6c1-2f69120569d6'	System	29 Jan 2021 00:18:12
User entered 'No (N)'	System	29 Jan 2021 00:18:12

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-01-28T19:18:04', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '5b8eb512-6066-4444-a6c1-2f69120569d6' User entered '28 Jan 2021 19:18:04'	System	29 Jan 2021 00:18:12
	System	29 Jan 2021 00:18:12

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-02-01T07:09:33', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '7d336f38-edc5-4210-b4ba-688241ff87e3' User entered 'No (N)'	System	01 Feb 2021 12:09:42
	System	01 Feb 2021 12:09:42

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-02-01T07:09:34', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '7d336f38-edc5-4210-b4ba-688241ff87e3'	System	01 Feb 2021 12:09:42
User entered 'No (N)'	System	01 Feb 2021 12:09:42

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-02-01T07:09:38', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '7d336f38-edc5-4210-b4ba-688241ff87e3'	System	01 Feb 2021 12:09:42
User entered '01 Feb 2021 07:09:38'	System	01 Feb 2021 12:09:42

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-02-07T20:01:11', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'adabdc4b-2e93-401d-bf3a-06728aa05cde' User entered 'No (N)'	System	08 Feb 2021 01:01:20
	System	08 Feb 2021 01:01:20

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-02-07T20:01:13', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'adabdc4b-2e93-401d-bf3a-06728aa05cde' User entered 'No (N)'	System	08 Feb 2021 01:01:20
	System	08 Feb 2021 01:01:20

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-02-07T20:01:17', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'adabdc4b-2e93-401d-bf3a-06728aa05cde' User entered '07 Feb 2021 20:01:17'	System	08 Feb 2021 01:01:20
	System	08 Feb 2021 01:01:20

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-02-15T08:37:28', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'd7f2e357-c65d-4091-a1cf-d5f74ff9214e' User entered 'No (N)'	System	15 Feb 2021 13:37:37
	System	15 Feb 2021 13:37:37

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-02-15T08:37:30', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'd7f2e357-c65d-4091-a1cf-d5f74ff9214e' User entered 'No (N)'	System	15 Feb 2021 13:37:37
	System	15 Feb 2021 13:37:37

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-02-15T08:37:33', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'd7f2e357-c65d-4091-a1cf-d5f74ff9214e' User entered '15 Feb 2021 08:37:33'	System	15 Feb 2021 13:37:37
	System	15 Feb 2021 13:37:37

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-02-22T08:56:35', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '8d5992d5-f43a-4fb1-a252-84621e139e01' User entered 'No (N)'	System	22 Feb 2021 13:56:48
	System	22 Feb 2021 13:56:48

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-02-22T08:56:41', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '8d5992d5-f43a-4fb1-a252-84621e139e01' User entered 'No (N)'	System	22 Feb 2021 13:56:48

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-02-22T08:56:45', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '8d5992d5-f43a-4fb1-a252-84621e139e01' User entered '22 Feb 2021 08:56:45'	System	22 Feb 2021 13:56:48
	System	22 Feb 2021 13:56:48

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-03-01T09:45:27', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '1ee444ce-badd-4ba4-808e-f22d1a771c87'	System	01 Mar 2021 14:45:40
User entered 'No (N)'	System	01 Mar 2021 14:45:40

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-03-01T09:45:30', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '1ee444ce-badd-4ba4-808e-f22d1a771c87'	System	01 Mar 2021 14:45:40
User entered 'No (N)'	System	01 Mar 2021 14:45:40

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-03-01T09:45:33', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '1ee444ce-badd-4ba4-808e-f22d1a771c87' User entered '01 Mar 2021 09:45:33'	System	01 Mar 2021 14:45:40
	System	01 Mar 2021 14:45:40

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-03-08T09:53:32-05:00', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '02b37e27-b879-431c-97c0-f11232c9dd32'	System	08 Mar 2021 14:53:46
User entered 'No (N)'	System	08 Mar 2021 14:53:46

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-03-08T09:53:36-05:00', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '02b37e27-b879-431c-97c0-f11232c9dd32'	System	08 Mar 2021 14:53:46
User entered 'No (N)'	System	08 Mar 2021 14:53:46

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-03-08T09:53:41-05:00', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '02b37e27-b879-431c-97c0-f11232c9dd32'	System	08 Mar 2021 14:53:46
User entered '08 Mar 2021 09:53:41'	System	08 Mar 2021 14:53:46

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-03-14T14:08:01-04:00', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '280954bc-cde6-42c0-8dd0-ad8435800df2'	System	14 Mar 2021 18:08:12
User entered 'No (N)'	System	14 Mar 2021 18:08:12

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-03-14T14:08:03-04:00', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '280954bc-cde6-42c0-8dd0-ad8435800df2'	System	14 Mar 2021 18:08:12
User entered 'No (N)'	System	14 Mar 2021 18:08:12

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-03-14T14:08:06-04:00', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '280954bc-cde6-42c0-8dd0-ad8435800df2'	System	14 Mar 2021 18:08:12
User entered '14 Mar 2021 14:08:06'	System	14 Mar 2021 18:08:12

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-03-21T12:51:58-04:00', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '270ebcd4-b140-45ef-8401-e44010737ead' User entered 'No (N)'	System	21 Mar 2021 16:52:08
	System	21 Mar 2021 16:52:08

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-03-21T12:52:01-04:00', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '270ebcd4-b140-45ef-8401-e44010737ead' User entered 'No (N)'	System	21 Mar 2021 16:52:08

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-03-21T12:52:04-04:00', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '270ebcd4-b140-45ef-8401-e44010737ead' User entered '21 Mar 2021 12:52:04'	System	21 Mar 2021 16:52:08
	System	21 Mar 2021 16:52:08

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-03-29T08:40:15-04:00', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '21f17758-bc72-4b66-8c33-94718b73f582'	System	29 Mar 2021 12:40:42
User entered 'No (N)'	System	29 Mar 2021 12:40:42

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-03-29T08:40:30-04:00', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '21f17758-bc72-4b66-8c33-94718b73f582'	System	29 Mar 2021 12:40:42
User entered 'No (N)'	System	29 Mar 2021 12:40:42

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-03-29T08:40:38-04:00', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '21f17758-bc72-4b66-8c33-94718b73f582' User entered '29 Mar 2021 08:40:38'	System	29 Mar 2021 12:40:42
	System	29 Mar 2021 12:40:42

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-04-07T10:55:49-04:00', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'c733c3e2-127c-4810-b2ef-dace50e65983' User entered 'No (N)'	System	07 Apr 2021 14:55:58
	System	07 Apr 2021 14:55:58

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-04-07T10:55:51-04:00', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'c733c3e2-127c-4810-b2ef-dace50e65983' User entered 'No (N)'	System	07 Apr 2021 14:55:58
	System	07 Apr 2021 14:55:58

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-04-07T10:55:54-04:00', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'c733c3e2-127c-4810-b2ef-dace50e65983' User entered '07 Apr 2021 10:55:54'	System	07 Apr 2021 14:55:58
	System	07 Apr 2021 14:55:58

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-04-12T06:51:16-04:00', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'fac31fad-3976-4d3d-aaf9-cc55bef5cc7e'	System	12 Apr 2021 10:51:24
User entered 'No (N)'	System	12 Apr 2021 10:51:24

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-04-12T06:51:18-04:00', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'fac31fad-3976-4d3d-aaf9-cc55bef5cc7e' User entered 'No (N)'	System	12 Apr 2021 10:51:24
	System	12 Apr 2021 10:51:24

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-04-12T06:51:21-04:00', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'fac31fad-3976-4d3d-aaf9-cc55bef5cc7e'	System	12 Apr 2021 10:51:24
User entered '12 Apr 2021 06:51:21'	System	12 Apr 2021 10:51:24

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-04-18T20:24:20-04:00', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '32093796-0729-4d70-a7cd-a2783bff2dcd' User entered 'No (N)'	System	19 Apr 2021 00:24:29
	System	19 Apr 2021 00:24:29

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-04-18T20:24:23-04:00', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '32093796-0729-4d70-a7cd-a2783bff2dcd' User entered 'No (N)'	System	19 Apr 2021 00:24:29
	System	19 Apr 2021 00:24:29

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-04-18T20:24:27-04:00', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '32093796-0729-4d70-a7cd-a2783bff2dcd' User entered '18 Apr 2021 20:24:27'	System	19 Apr 2021 00:24:29
	System	19 Apr 2021 00:24:29

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-04-26T22:42:16-04:00', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '49af15f2-2fac-493d-baa0-3b28931fa2a2'	System	27 Apr 2021 02:42:27
User entered 'No (N)'	System	27 Apr 2021 02:42:27

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-04-26T22:42:18-04:00', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '49af15f2-2fac-493d-baa0-3b28931fa2a2'	System	27 Apr 2021 02:42:27
User entered 'No (N)'	System	27 Apr 2021 02:42:27

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-04-26T22:42:22-04:00', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '49af15f2-2fac-493d-baa0-3b28931fa2a2'	System	27 Apr 2021 02:42:27
User entered '26 Apr 2021 22:42:22'	System	27 Apr 2021 02:42:27

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-05-02T14:41:50-04:00', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '3953f018-3c31-46ba-a86b-262204b42430'	System	02 May 2021 18:41:59
User entered 'No (N)'	System	02 May 2021 18:41:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Have you been exposed to someone with 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 (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-05-02T14:41:52-04:00', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '3953f018-3c31-46ba-a86b-262204b42430'	System	02 May 2021 18:41:59
User entered 'No (N)'	System	02 May 2021 18:41:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-05-02T14:41:56-04:00', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: '3953f018-3c31-46ba-a86b-262204b42430'	System	02 May 2021 18:41:59
User entered '02 May 2021 14:41:56'	System	02 May 2021 18:41:59

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 03:49:31

US3512217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:49:31
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 03:49:31

US3512217

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 07:55:38

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 14:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-03-01T09:45:14', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'a0d4655a-438c-442a-8011-91d27d226621'	System	01 Mar 2021 14:45:22
User entered 'No (N)'	System	01 Mar 2021 14:45:22

US3512217

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 07:55:38

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C9A28422-0AED-4603-8868-D6BA92777892)', Time: '2021-03-01T09:45:18', User OID: 'PatientReportedOutcome (US3512217)', ODM File OID: 'a0d4655a-438c-442a-8011-91d27d226621' User entered '01 Mar 2021 09:45:18'	System	01 Mar 2021 14:45:22
	System	01 Mar 2021 14:45:22

US3512217

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	14 Dec 2020 15:52:54
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	30 Nov 2020 23:06:51
	(b) (4)	

US3512217

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 15:52:54
User entered '30 Nov 2020'	Sheldon Warren (b) (4) (b) (4)	30 Nov 2020 23:06:51

US3512217

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	14 Dec 2020 15:52:54
User entered 'Contact Made (CONTACT MADE)'	Sheldon Warren (b) (4)	30 Nov 2020 23:06:51
	(b) (4)	

US3512217

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 15:52:54
User entered empty.	Sheldon Warren (b) (4) (b) (4)	30 Nov 2020 23:06:51

US3512217

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	14 Dec 2020 15:52:58
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	30 Nov 2020 23:06:55
	(b) (4)	

US3512217

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:13:39
User entered 'I'	System	30 Nov 2020 23:06:55

US3512217

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:08:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:16:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	11 Jan 2021 23:11:39

US3512217

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:08:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:16:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered '11 Jan 2021'	(b) (4) Sheldon Warren (b) (4) (b) (4)	11 Jan 2021 23:11:39

US3512217

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:08:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:16:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	11 Jan 2021 23:11:39

US3512217

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:08:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:16:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered empty.	(b) (4) Sheldon Warren (b) (4) (b) (4)	11 Jan 2021 23:11:39

US3512217

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:08:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:17:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	11 Jan 2021 23:11:45

US3512217

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:08:51
User entered '1'	System	11 Jan 2021 23:11:45

US3512217

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:08:51
User closed query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample collected on 29JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Michael Koren (b) (4)	15 Feb 2021 19:49:40 12 Feb 2021 21:53:30
Query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample collected on 29JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' answered with 'Added to EDC' (Site from DM).	Allison Crain (b) (4) (b) (4)	11 Feb 2021 18:54:04
User opened query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample collected on 29JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Feb 2021 02:07:25 08 Feb 2021 19:04:41
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	29 Jan 2021 15:42:01

US3512217

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:08:51
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 19:04:41
User entered '29 Jan 2021'	Sheldon Warren (b) (4)	29 Jan 2021 15:42:01

US3512217

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:08:51
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:04:41
User entered 'Contact Made (CONTACT MADE)'	Sheldon Warren (b) (4) (b) (4)	29 Jan 2021 15:42:01

US3512217

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:08:51
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:04:41
User entered empty.	Sheldon Warren (b) (4) (b) (4)	29 Jan 2021 15:42:01

US3512217

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:08:51
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Immuno 8 Sample dated 29Jan2021 is recorded under OL-1 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:50:00
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Immuno 8 Sample dated 29Jan2021 is recorded under OL-1 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' answered with 'added to edc' (Site from DM).	Allison Crain (b) (4) (b) (4)	11 Feb 2021 18:53:46
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Immuno 8 Sample dated 29Jan2021 is recorded under OL-1 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 12:10:00
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 19:04:47
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	29 Jan 2021 15:42:06

US3512217

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:08:51
User entered 'I'	System	29 Jan 2021 15:42:06

US3512217

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:08:51
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:30:08
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:01
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	26 Feb 2021 19:54:25

US3512217

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:08:51
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:30:08
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:01
User entered '26 Feb 2021'	(b) (4) Sheldon Warren (b) (4) (b) (4)	26 Feb 2021 19:54:25

US3512217

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:08:51
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:30:08
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	26 Feb 2021 19:54:25

US3512217

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:08:51
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:30:08
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:01
User entered empty.	(b) (4) Sheldon Warren (b) (4) (b) (4)	26 Feb 2021 19:54:25

US3512217

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:08:51
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:30:17
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:01
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	26 Feb 2021 19:54:31

US3512217

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:08:51
User entered 'I'	System	26 Feb 2021 19:54:31

US3512217

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:54:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:58:15
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:23:36

US3512217

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:54:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:58:15
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered '02 Apr 2021'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:23:36

US3512217

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:54:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:58:15
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:23:36

US3512217

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:54:11
User entered 'VISIT4'	System	02 Apr 2021 15:23:36

US3512217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:54:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:58:26
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:23:47

US3512217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:54:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:58:26
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:23:47

US3512217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:54:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:58:26
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:23:47

US3512217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:54:11
User entered empty.	System	02 Apr 2021 15:23:47

US3512217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:54:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:58:26
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:23:47

US3512217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:54:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:58:26
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:23:47

US3512217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:54:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:58:26
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:23:47

US3512217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:54:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:58:26
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:23:47

US3512217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:54:11
User entered empty.	System	02 Apr 2021 15:23:47

US3512217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:54:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:58:26
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:23:47

US3512217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:54:11
User entered empty.	System	02 Apr 2021 15:23:47

US3512217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:54:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:58:26
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:23:47

US3512217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:54:11
User entered empty.	System	02 Apr 2021 15:23:47

US3512217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:54:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:58:26
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:23:47

US3512217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:54:11
User entered empty.	System	02 Apr 2021 15:23:47

US3512217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:54:11

US3512217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:54:11

US3512217

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:55:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:54:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:58:30
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:23:42

US3512217

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:55:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:54:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:58:30
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:23:42

US3512217

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:54:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:58:38
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:24:00

US3512217

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:54:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:58:38
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered '02 Apr 2021'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:24:00

US3512217

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:54:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:58:38
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered '10:54'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:24:00

US3512217

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:54:11
User entered '02 Apr 2021 10:54'	System	02 Apr 2021 15:24:00

US3512217

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:54:11
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 17:58:42
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	05 Apr 2021 13:24:03
	(b) (4)	

US3512217

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:54:11
User entered '1'	System	05 Apr 2021 13:24:03

US3512217

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	03 May 2021 15:13:59
	(b) (4)	
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	29 Apr 2021 20:45:51
	(b) (4)	

US3512217

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	03 May 2021 15:13:59
	(b) (4)	
User entered '27 Apr 2021'	Sheldon Warren (b) (4)	29 Apr 2021 20:45:51
	(b) (4)	

US3512217

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	03 May 2021 15:13:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	29 Apr 2021 20:45:51

US3512217

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	03 May 2021 15:13:59
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	29 Apr 2021 20:45:51
	(b) (4)	

US3512217

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	03 May 2021 15:13:59
	(b) (4)	
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	29 Apr 2021 20:45:55
	(b) (4)	

US3512217

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 20:45:55

US3512217

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

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:32:47
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:17:40
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4) (b) (4)	11 Feb 2021 18:52:16

US3512217

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

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:32:47
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:17:40
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered '29 Jan 2021'	(b) (4) Allison Crain (b) (4) (b) (4)	11 Feb 2021 18:52:16

US3512217

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

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[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 14:32:47
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:17:40
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'Clinic (Clinic)'	(b) (4) Allison Crain (b) (4) (b) (4)	11 Feb 2021 18:52:16

US3512217

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

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:32:47
User entered 'UNBLND_DECIDE'	System	11 Feb 2021 18:52:16

US3512217

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

Form: Unblinding

Generated On: 10 Jun 2021 07:55:38

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:32:47
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:18:13
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered '29 Jan 2021'	(b) (4) Allison Crain (b) (4) (b) (4)	11 Feb 2021 18:52:41

US3512217

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

Form: Unblinding

Generated On: 10 Jun 2021 07:55:38

[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 14:32:47
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:51:20
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:41:55

US3512217

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

Form: Unblinding

Generated On: 10 Jun 2021 07:55:38

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:32:47
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:18:13
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4) (b) (4)	11 Feb 2021 18:52:41

US3512217

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

Form: Unblinding

Generated On: 10 Jun 2021 07:55:38

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:32:47
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:51:20
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 14:41:55

US3512217

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

Form: Unblinding

Generated On: 10 Jun 2021 07:55:38

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:32:47
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:18:13
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered '29 Jan 2021'	(b) (4) Allison Crain (b) (4) (b) (4)	11 Feb 2021 18:52:41

US3512217

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

Form: Unblinding

Generated On: 10 Jun 2021 07:55:38

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:32:47
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:18:13
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'mRNA-1273 (mRNA-1273)'	Allison Crain (b) (4)	11 Feb 2021 18:52:41

US3512217

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

Form: Unblinding

Generated On: 10 Jun 2021 07:55:38

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:32:47
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:18:13
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Allison Crain (b) (4) (b) (4)	11 Feb 2021 18:52:41

US3512217

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

Form: Unblinding

Generated On: 10 Jun 2021 07:55:38

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:32:47
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:18:13
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Allison Crain (b) (4) (b) (4)	11 Feb 2021 18:52:41

US3512217

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

Form: Unblinding

Generated On: 10 Jun 2021 07:55:38

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:32:47
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:18:13
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'No (N)'	(b) (4) Allison Crain (b) (4) (b) (4)	11 Feb 2021 18:52:41

US3512217

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

Form: Unblinding

Generated On: 10 Jun 2021 07:55:38

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:32:47
User entered empty.	System	11 Feb 2021 18:52:41

US3512217

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

Form: Unblinding

Generated On: 10 Jun 2021 07:55:38

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:32:47
User entered empty.	System	11 Feb 2021 18:52:41

US3512217

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:32:47
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:57:54
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4) (b) (4)	11 Feb 2021 18:53:01

US3512217

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:32:47
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:57:54
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered '29 Jan 2021'	(b) (4) Allison Crain (b) (4) (b) (4)	11 Feb 2021 18:53:01

US3512217

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:32:47
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:57:54
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered '10:34'	(b) (4) Allison Crain (b) (4) (b) (4)	11 Feb 2021 18:53:01

US3512217

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:32:47
User entered '29 Jan 2021 10:34'	System	11 Feb 2021 18:53:01

US3512217

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:55:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:32:47
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:18:40
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4) (b) (4)	11 Feb 2021 18:53:15

US3512217

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:32:47
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:18:40
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered '29 Jan 2021'	(b) (4) Allison Crain (b) (4) (b) (4)	11 Feb 2021 18:53:15

US3512217

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:55:38

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:32:47
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:18:40
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered '10:30'	(b) (4) Allison Crain (b) (4) (b) (4)	11 Feb 2021 18:53:15

US3512217

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:32:47
User entered '29 Jan 2021 10:30'	System	11 Feb 2021 18:53:15

US3512217

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 07:55:38

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	29 Sep 2020 14:33:50

US3512217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54

US3512217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:37:25
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 14:36:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 14:36:36
Data point term sent to Coder	System	29 Sep 2020 14:35:45
User entered 'Low back pain'	Sheldon Warren (b) (4) (b) (4)	29 Sep 2020 14:35:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered 'No (N)'	Sheldon Warren (b) (4)	29 Sep 2020 14:35:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered 'No (N)'	Sheldon Warren (b) (4)	29 Sep 2020 14:35:07
	(b) (4)	

US3512217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	29 Sep 2020 14:35:07

US3512217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered '16 Sep 2020'	Sheldon Warren (b) (4)	29 Sep 2020 14:35:07
	(b) (4)	

US3512217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered empty.	Sheldon Warren (b) (4)	29 Sep 2020 14:35:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54
User entered empty.	System	29 Sep 2020 14:35:07

US3512217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered 'No (N)'	Sheldon Warren (b) (4)	29 Sep 2020 14:35:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered '26 Sep 2020'	Sheldon Warren (b) (4)	29 Sep 2020 14:35:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	26 Jan 2021 20:37:25
User entered empty.	Sheldon Warren (b) (4)	29 Sep 2020 14:35:07

US3512217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54
User entered empty.	System	29 Sep 2020 14:35:07

US3512217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Sheldon Warren (b) (4)	29 Sep 2020 14:35:07
	(b) (4)	

US3512217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered 'No (N)'	Sheldon Warren (b) (4)	29 Sep 2020 14:35:07
	(b) (4)	

US3512217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered '0'	Sheldon Warren (b) (4)	29 Sep 2020 14:35:07
	(b) (4)	

US3512217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered '0'	Sheldon Warren (b) (4)	29 Sep 2020 14:35:07
	(b) (4)	

US3512217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered '0'	Sheldon Warren (b) (4)	29 Sep 2020 14:35:07
	(b) (4)	

US3512217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Sheldon Warren (b) (4)	29 Sep 2020 14:35:07
	(b) (4)	

US3512217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered empty.	Sheldon Warren (b) (4)	29 Sep 2020 14:35:07
	(b) (4)	

US3512217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered empty.	Sheldon Warren (b) (4)	29 Sep 2020 14:35:07
	(b) (4)	

US3512217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Sheldon Warren (b) (4)	29 Sep 2020 14:35:07
	(b) (4)	

US3512217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered '0'	Sheldon Warren (b) (4)	29 Sep 2020 14:35:07
	(b) (4)	

US3512217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '0'	Sheldon Warren (b) (4)	29 Sep 2020 14:35:07
	(b) (4)	

US3512217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered '0'	Sheldon Warren (b) (4)	29 Sep 2020 14:35:07
	(b) (4)	

US3512217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered 'Not Related (NOT RELATED)'	Sheldon Warren (b) (4)	29 Sep 2020 14:35:07
	(b) (4)	

US3512217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered 'Not Related (NOT RELATED)'	Sheldon Warren (b) (4)	29 Sep 2020 14:35:07
	(b) (4)	

US3512217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered 'None (NONE)'	Sheldon Warren (b) (4)	29 Sep 2020 14:35:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered '0'	Sheldon Warren (b) (4)	29 Sep 2020 14:35:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'l'	Sheldon Warren (b) (4)	29 Sep 2020 14:35:07
	(b) (4)	

US3512217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered '0'	Sheldon Warren (b) (4)	29 Sep 2020 14:35:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sheldon Warren (b) (4)	29 Sep 2020 14:35:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered empty.	Sheldon Warren (b) (4)	29 Sep 2020 14:35:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered empty.	Sheldon Warren (b) (4)	29 Sep 2020 14:35:07
	(b) (4)	

US3512217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54
User entered '0'	System	29 Sep 2020 14:35:07

US3512217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54
User entered '0'	System	29 Sep 2020 14:35:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:16:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	26 Jan 2021 20:37:25
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:37
	(b) (4), (b) (6)	
User entered	System	06 Jan 2021 16:25:32
'USA-US065-2021-mRNA-1273-P301000001'		
User entered 'New' reason for change: New Information	(b) (4), (b) (6)	06 Jan 2021 16:25:32
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 16:25:15

US3512217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User closed query 'PV Query: Please consider updating the event term to the cause of the syncopal episode, if known. If term is to remain as syncopal episode please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:48:43
Query 'PV Query: Please consider updating the event term to the cause of the syncopal episode, if known. If term is to remain as syncopal episode please state so.' answered with 'unknown cause of syncopal episode per medical records; confirmed as is.' (Site from Safety).	Allison Crain (b) (4) (b) (4)	16 Feb 2021 14:29:36
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User opened query 'PV Query: Please consider updating the event term to the cause of the syncopal episode, if known. If term is to remain as syncopal episode please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 14:20:46
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Syncope, LLT: Syncopal attack - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Jan 2021 02:26:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Jan 2021 02:26:40
Data point term sent to Coder	System	06 Jan 2021 02:25:25
User entered 'Syncopal Episode'	(b) (4), (b) (6)	06 Jan 2021 02:25:13

US3512217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 02:25:13

US3512217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered 'No (N)'	(b) (4), (b) (6)	06 Jan 2021 02:25:13

US3512217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered 'No (N)'	(b) (4), (b) (6)	06 Jan 2021 02:25:13

US3512217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered '31 Dec 2020'	(b) (4), (b) (6)	06 Jan 2021 02:25:13

US3512217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 02:25:13

US3512217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Jan 2021 02:25:13

US3512217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered 'No (N)'	(b) (4), (b) (6)	06 Jan 2021 02:25:13

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 17:57:28
User closed query 'Per DM CLR: Please review the dates of this AE as it is not expected that an episode of syncope would have a duration of more than a single date. Please reconcile and update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 06:05:18
Query 'Per DM CLR: Please review the dates of this AE as it is not expected that an episode of syncope would have a duration of more than a single date. Please reconcile and update as appropriate. Otherwise, clarify.' answered with 'changed per query' (Site from DM).	Brenda Anderson (b) (4)	05 Apr 2021 14:27:07
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	Brenda Anderson (b) (4)	05 Apr 2021 14:26:37
	(b) (4)	
User entered '31 Dec 2020' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Apr 2021 14:26:37
User opened query 'Per DM CLR: Please review the dates of this AE as it is not expected that an episode of syncope would have a duration of more than a single date. Please reconcile and update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 19:28:54
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	06 Jan 2021 15:26:15
User entered '02 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Jan 2021 15:26:15
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	06 Jan 2021 02:25:13
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 02:25:13

US3512217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 02:25:13

US3512217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Jan 2021 02:25:13

US3512217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:57:28
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User closed query 'PV Query: Since the subject was hospitalized for the event of syncopal episode, appropriate CTCAE grade should be grade 3 instead of grade 1/grade 2. Please update the event severity as such. If the severity is to remain grade 1/grade 2, please clarify/explain.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:56:10
Query 'PV Query: Since the subject was hospitalized for the event of syncopal episode, appropriate CTCAE grade should be grade 3 instead of grade 1/grade 2. Please update the event severity as such. If the severity is to remain grade 1/grade 2, please clarify/explain.' answered with 'updated' (Site from Safety).	Allison Crain (b) (4) (b) (4)	05 Mar 2021 17:07:08
DataPoint Un-verified.	Allison Crain (b) (4) (b) (4)	05 Mar 2021 17:06:59
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	05 Mar 2021 17:06:59
User opened query 'PV Query: Since the subject was hospitalized for the event of syncopal episode, appropriate CTCAE grade should be grade 3 instead of grade 1/grade 2. Please update the event severity as such. If the severity is to remain grade 1/grade 2, please clarify/explain.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 15:33:59
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 15:26:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Jan 2021 15:26:15
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Jan 2021 15:26:15
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 02:25:13
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 02:25:13

US3512217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 02:25:13

US3512217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered '0'	(b) (4), (b) (6)	06 Jan 2021 02:25:13

US3512217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered '0'	(b) (4), (b) (6)	06 Jan 2021 02:25:13

US3512217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered 'I'	(b) (4), (b) (6)	06 Jan 2021 02:25:13

US3512217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered '31 Dec 2020'	(b) (4), (b) (6)	06 Jan 2021 02:25:13

US3512217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 20:01:25
Query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' answered with 'being worked up for cause of syncope' (Site from Safety).	Brenda Anderson (b) (4)	12 Apr 2021 12:40:11
User opened query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 11:40:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Jan 2021 15:26:15
User entered '02 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Jan 2021 15:26:15
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Jan 2021 02:25:13
User entered 'UN Jan 2021' (non-conformant).	(b) (4), (b) (6)	06 Jan 2021 02:25:13

US3512217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:37:25
User closed query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	06 Jan 2021 15:26:15
Query 'Admitted to ICU?' is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		06 Jan 2021 15:26:15
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Jan 2021 15:26:15
User opened query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	06 Jan 2021 02:25:13
User entered 'Unknown (UNK)'	(b) (4), (b) (6)	06 Jan 2021 02:25:13

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 02:25:13

US3512217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered '0'	(b) (4), (b) (6)	06 Jan 2021 02:25:13

US3512217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered '0'	(b) (4), (b) (6)	06 Jan 2021 02:25:13

US3512217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered '0'	(b) (4), (b) (6)	06 Jan 2021 02:25:13

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 16:25:10
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'data updated' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 15:27:51
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 15:26:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Jan 2021 15:26:15
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Jan 2021 15:26:15
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 14:08:27
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 02:25:13
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 02:25:13

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 16:25:12
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'data updated' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 15:27:58
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 15:26:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Jan 2021 15:26:15
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Jan 2021 15:26:15
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 15:10:49
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 02:25:13
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 02:25:13

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Folder: Adverse Events

Form: Adverse Events (2)

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 21:18:51
	(b) (4), (b) (6)	11 Feb 2021 04:42:27
User closed query 'Per CDM: As the Adverse event started after last dose, please review and update the action taken with study drug from None to Not Applicable. ' (Site from DM).		
Query 'Per CDM: As the Adverse event started after last dose, please review and update the action taken with study drug from None to Not Applicable. ' answered with 'UPDATED' (Site from DM).	Allison Crain (b) (4)	09 Feb 2021 18:06:50
	(b) (4)	
DataPoint Un-verified.	Allison Crain (b) (4)	09 Feb 2021 18:06:39
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Allison Crain (b) (4)	09 Feb 2021 18:06:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 20:37:25
	(b) (4), (b) (6)	13 Jan 2021 05:21:49
User opened query 'Per CDM: As the Adverse event started after last dose, please review and update the action taken with study drug from None to Not Applicable. ' (Site from DM).		
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 15:26:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Jan 2021 15:26:15
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Jan 2021 15:26:15
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 02:25:13
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 02:25:13

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Folder: Adverse Events

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None

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	16 Feb 2021 13:03:35
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Feb 2021 12:22:46
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	06 Jan 2021 15:27:40
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	06 Jan 2021 02:25:13
User entered '0'	(b) (4), (b) (6)	06 Jan 2021 02:25:13

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 21:18:51
DataPoint Un-verified.	Allison Crain (b) (4)	16 Feb 2021 13:03:35
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Allison Crain (b) (4)	16 Feb 2021 13:03:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered '0'	(b) (4), (b) (6)	06 Jan 2021 02:25:13

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 21:18:51
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 08:27:38
Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'No therapeutic conproc done' (Site from DM).	Allison Crain (b) (4)	16 Feb 2021 13:03:20
	(b) (4)	
DataPoint Un-verified.	Allison Crain (b) (4)	16 Feb 2021 12:22:46
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Allison Crain (b) (4)	16 Feb 2021 12:22:46
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 03:08:37
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Jan 2021 15:27:40
User entered '0'	(b) (4), (b) (6)	06 Jan 2021 02:25:13

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 15:26:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Jan 2021 15:26:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	06 Jan 2021 15:26:15
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 02:25:13
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 02:25:13

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:37:25
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 02:25:13

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Thank you for reporting that the subject remained hospitalized for work-up for the cause of syncope. Please provide the work-up results and the final diagnosis, if available.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 21:36:49
User closed query 'PV Query: Reported event of syncope and COVID-19 (paper SAE form) occurred on the same dates. Per paper report, no COVID-19 test was collected. Was the subject diagnosed with COVID-19? If so, please report a separate event for COVID -19 or reconcile event terms. Thank you.' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 14:44:40
Query 'PV Query: Reported event of syncope and COVID-19 (paper SAE form) occurred on the same dates. Per paper report, no COVID-19 test was collected. Was the subject diagnosed with COVID-19? If so, please report a separate event for COVID -19 or reconcile event terms. Thank you.' answered with 'Please see revised paper SAE report form. patient did not get diagnosed with Covid-19 and no testing was performed.' (Site from Safety).	Allison Crain (b) (4) (b) (4)	16 Mar 2021 12:49:42
User opened query 'PV Query: Reported event of syncope and COVID-19 (paper SAE form) occurred on the same dates. Per paper report, no COVID-19 test was collected. Was the subject diagnosed with COVID-19? If so, please report a separate event for COVID -19 or reconcile event terms. Thank you.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 16:18:17
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so:.' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 16:02:06
User signature succeeded.	Michael Koren (b) (4) (b) (4)	05 Mar 2021 22:43:41

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Please see ConMed log line #10 and see follow up report. No further medications given.' (Site from Safety). DataPoint Verified.	Allison Crain (b) (4) (b) (4)	05 Mar 2021 17:54:52
	(b) (4), (b) (6)	23 Feb 2021 21:18:51
User closed query 'PV Query: Please provide the etiology/underlying cause for the syncopal episode if known. If unknown, please state so.' (Site from Safety).	(b) (4), (b) (6)	17 Feb 2021 15:48:51
Query 'PV Query: Please provide the etiology/underlying cause for the syncopal episode if known. If unknown, please state so.' answered with 'unknown per medical records' (Site from Safety). DataPoint Un-verified.	Allison Crain (b) (4) (b) (4)	16 Feb 2021 14:28:55
	Allison Crain (b) (4) (b) (4)	16 Feb 2021 14:28:42
User entered 'SUBJECT REPORTED HOSPITALIZATION ON 31DEC2020 DUE TO SYNCOPAL EPISODE. Underlying cause unknown per medical records.' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	16 Feb 2021 14:28:42
User closed query 'PV Query: Please confirm the subject experienced COVID-19 (reported in paper SAE form). If yes, please add SAE to the EDC as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 16:22:51
User closed query 'PV Query: Please complete the COVID-19 Assessments tab, including results of COVID-19 diagnostic test, symptoms log, and severity assessment.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 16:22:48
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 16:22:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 16:22:39
Query 'PV Query: PV Query: Please complete the COVID-19 Assessments tab, including results of COVID-19 diagnostic test, symptoms log, and severity assessment.' answered with 'This is not a confirmed Covid-19 diagnosis, reported incorrectly, will send updated SAE follow up form.' (Site from Safety).	Allison Crain (b) (4) (b) (4)	09 Feb 2021 19:25:17
Query 'PV Query: Please confirm the subject experienced COVID-19 (reported in paper SAE form). If yes, please add SAE to the EDC as soon as possible.' answered with 'Error of reporting, this is not a confirmed covid-19 diagnosis. Will send updated SAE form.' (Site from Safety).	Allison Crain (b) (4) (b) (4)	09 Feb 2021 19:24:43
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Sent to IQVIA via email.' (Site from Safety).	Allison Crain (b) (4) (b) (4)	09 Feb 2021 19:23:34
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'No Covid-19 testing collected' (Site from Safety).	Allison Crain (b) (4) (b) (4)	09 Feb 2021 18:36:53
User opened query 'PV Query: PV Query: Please complete the COVID-19 Assessments tab, including results of COVID-19 diagnostic test, symptoms log, and severity assessment.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 12:51:43
User opened query 'PV Query: Please confirm the subject experienced COVID-19 (reported in paper SAE form). If yes, please add SAE to the EDC as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 12:51:37
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 20:37:25
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 14:20:59

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the etiology/underlying cause for the syncopal episode if known. If unknown, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 14:20:37
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 14:20:20
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 14:20:14
User entered 'Subject reported hospitalization on 31DEC2020 due to Syncopal Episode'	(b) (4), (b) (6)	06 Jan 2021 02:25:13

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Folder: Adverse Events

Form: Adverse Events (2)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 02:25:13

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Folder: Adverse Events

Form: Adverse Events (2)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 02:25:13

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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)
User entered '0'	System	06 Jan 2021 02:25:13

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 17:57:28
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Site specific injuries NEC, PT: Neck injury, LLT: Neck injury - version MedDRA\23.0.	Coder Import (b) (4)	02 Apr 2021 20:55:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Apr 2021 20:55:39
Data point term sent to Coder	System	02 Apr 2021 20:54:49
User closed query 'DM-Coding: For AE term NECK AND RIGHT SHOULDER INJURY, Please provide a unifying diagnosis for this reported event or split to report each event into a separate record, example: 1) NECK INJURY 2) RIGHT SHOULDER INJURY etc.	System	02 Apr 2021 20:54:22
' (Site from System).		
Query 'DM-Coding: For AE term NECK AND RIGHT SHOULDER INJURY, Please provide a unifying diagnosis for this reported event or split to report each event into a separate record, example: 1) NECK INJURY 2) RIGHT SHOULDER INJURY etc.	Brenda Anderson (b) (4)	02 Apr 2021 20:54:22
' answered with 'corrected per query' (Site from System).	(b) (4)	
Signature has been broken.	Brenda Anderson (b) (4)	02 Apr 2021 20:54:04
	(b) (4)	
User entered 'NECK injury' reason for change: Data Entry Error	Brenda Anderson (b) (4)	02 Apr 2021 20:54:04
	(b) (4)	
User opened query 'DM-Coding: For AE term NECK AND RIGHT SHOULDER INJURY, Please provide a unifying diagnosis for this reported event or split to report each event into a separate record, example: 1) NECK INJURY 2) RIGHT SHOULDER INJURY etc.	Coder Import (b) (4)	18 Mar 2021 14:36:39
' (Site from System).	(b) (4)	
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
	(b) (4)	
Data point term sent to Coder	System	05 Mar 2021 17:58:15
User entered 'NECK AND RIGHT SHOULDER INJURY'	Allison Crain (b) (4)	05 Mar 2021 17:58:10
	(b) (4)	

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Folder: Adverse Events

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:57:28
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered 'Yes (Y)'	Allison Crain (b) (4)	05 Mar 2021 17:58:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:57:28
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered 'No (N)'	Allison Crain (b) (4)	05 Mar 2021 17:58:10

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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)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:57:28
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered 'No (N)'	Allison Crain (b) (4)	05 Mar 2021 17:58:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:57:28
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered '31 Dec 2020'	Allison Crain (b) (4)	05 Mar 2021 17:58:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:57:28
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered empty.	Allison Crain (b) (4)	05 Mar 2021 17:58:10

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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)
User entered empty.	System	05 Mar 2021 17:58:10

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Folder: Adverse Events

Form: Adverse Events (3)

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:57:28
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered 'No (N)'	Allison Crain (b) (4)	05 Mar 2021 17:58:10

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Folder: Adverse Events

Form: Adverse Events (3)

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If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:57:28
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered '4 Feb 2021'	Allison Crain (b) (4)	05 Mar 2021 17:58:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:57:28
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered empty.	Allison Crain (b) (4)	05 Mar 2021 17:58:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 17:58:10

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Folder: Adverse Events

Form: Adverse Events (3)

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:57:28
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Allison Crain (b) (4)	05 Mar 2021 17:58:10

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:57:28
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered 'No (N)'	Allison Crain (b) (4)	05 Mar 2021 17:58:10

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Folder: Adverse Events

Form: Adverse Events (3)

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:57:28
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered '0'	Allison Crain (b) (4)	05 Mar 2021 17:58:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:57:28
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered '0'	Allison Crain (b) (4)	05 Mar 2021 17:58:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:57:28
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered '0'	Allison Crain (b) (4)	05 Mar 2021 17:58:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:57:28
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered empty.	Allison Crain (b) (4)	05 Mar 2021 17:58:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:57:28
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered empty.	Allison Crain (b) (4)	05 Mar 2021 17:58:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:57:28
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered empty.	Allison Crain (b) (4)	05 Mar 2021 17:58:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:57:28
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered empty.	Allison Crain (b) (4)	05 Mar 2021 17:58:10

US3512217

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:57:28
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered '0'	Allison Crain (b) (4)	05 Mar 2021 17:58:10

US3512217

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:57:28
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered '0'	Allison Crain (b) (4)	05 Mar 2021 17:58:10

US3512217

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:57:28
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered '0'	Allison Crain (b) (4)	05 Mar 2021 17:58:10

US3512217

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:57:28
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered 'Not Related (NOT RELATED)'	Allison Crain (b) (4)	05 Mar 2021 17:58:10

US3512217

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:57:28
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered 'Not Related (NOT RELATED)'	Allison Crain (b) (4)	05 Mar 2021 17:58:10

US3512217

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:57:28
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered 'Not Applicable (NOT APPLICABLE)'	Allison Crain (b) (4)	05 Mar 2021 17:58:10

US3512217

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:57:28
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered '0'	Allison Crain (b) (4)	05 Mar 2021 17:58:10

US3512217

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:57:28
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered 'I'	Allison Crain (b) (4)	05 Mar 2021 17:58:10

US3512217

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:57:28
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered '0'	Allison Crain (b) (4)	05 Mar 2021 17:58:10

US3512217

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:57:28
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Allison Crain (b) (4)	05 Mar 2021 17:58:10

US3512217

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:57:28
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered empty.	Allison Crain (b) (4)	05 Mar 2021 17:58:10

US3512217

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:57:28
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered empty.	Allison Crain (b) (4)	05 Mar 2021 17:58:10

US3512217

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Mar 2021 17:58:10

US3512217

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Mar 2021 17:58:10

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 17:57:28
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Site specific injuries NEC, PT: Limb injury, LLT: Shoulder injury - version MedDRA\\23.0.	Coder Import (b) (4)	02 Apr 2021 20:57:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Apr 2021 20:57:56
Data point term sent to Coder	System	02 Apr 2021 20:56:51
User entered 'RIGHT SHOULDER INJURY'	Brenda Anderson (b) (4)	02 Apr 2021 20:55:59
	(b) (4)	

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:57:28
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	02 Apr 2021 20:55:59

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:57:28
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	02 Apr 2021 20:55:59

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:57:28
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	02 Apr 2021 20:55:59

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:57:28
User entered '31 Dec 2020'	Brenda Anderson (b) (4) (b) (4)	02 Apr 2021 20:55:59

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:57:28
User entered empty.	Brenda Anderson (b) (4) (b) (4)	02 Apr 2021 20:55:59

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 20:55:59

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:57:28
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	02 Apr 2021 20:55:59

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:57:28
User entered '4 Feb 2021'	Brenda Anderson (b) (4) (b) (4)	02 Apr 2021 20:55:59

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:57:28
User entered empty.	Brenda Anderson (b) (4) (b) (4)	02 Apr 2021 20:55:59

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 20:55:59

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:57:28
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Brenda Anderson (b) (4) (b) (4)	02 Apr 2021 20:55:59

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:57:28
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	02 Apr 2021 20:55:59

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:57:28
User entered '0'	Brenda Anderson (b) (4) (b) (4)	02 Apr 2021 20:55:59

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:57:28
User entered '0'	Brenda Anderson (b) (4) (b) (4)	02 Apr 2021 20:55:59

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:57:28
User entered '0'	Brenda Anderson (b) (4) (b) (4)	02 Apr 2021 20:55:59

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:57:28
User entered empty.	Brenda Anderson (b) (4) (b) (4)	02 Apr 2021 20:55:59

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:57:28
User entered empty.	Brenda Anderson (b) (4) (b) (4)	02 Apr 2021 20:55:59

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:57:28
User entered empty.	Brenda Anderson (b) (4) (b) (4)	02 Apr 2021 20:55:59

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:57:28
User entered empty.	Brenda Anderson (b) (4) (b) (4)	02 Apr 2021 20:55:59

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:57:28
User entered '0'	Brenda Anderson (b) (4) (b) (4)	02 Apr 2021 20:55:59

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:57:28
User entered '0'	Brenda Anderson (b) (4) (b) (4)	02 Apr 2021 20:55:59

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:57:28
User entered '0'	Brenda Anderson (b) (4) (b) (4)	02 Apr 2021 20:55:59

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:57:28
User entered 'Not Related (NOT RELATED)'	Brenda Anderson (b) (4) (b) (4)	02 Apr 2021 20:55:59

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:57:28
User entered 'Not Related (NOT RELATED)'	Brenda Anderson (b) (4) (b) (4)	02 Apr 2021 20:55:59

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:57:28
User entered 'Not Applicable (NOT APPLICABLE)'	Brenda Anderson (b) (4) (b) (4)	02 Apr 2021 20:55:59

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

None

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:57:28
User entered '0'	Brenda Anderson (b) (4) (b) (4)	02 Apr 2021 20:55:59

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:57:28
User entered 'I'	Brenda Anderson (b) (4) (b) (4)	02 Apr 2021 20:55:59

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:57:28
User entered '0'	Brenda Anderson (b) (4) (b) (4)	02 Apr 2021 20:55:59

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:57:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Brenda Anderson (b) (4) (b) (4)	02 Apr 2021 20:55:59

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:57:28
User entered empty.	Brenda Anderson (b) (4) (b) (4)	02 Apr 2021 20:55:59

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:57:28
User entered empty.	Brenda Anderson (b) (4) (b) (4)	02 Apr 2021 20:55:59

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Apr 2021 20:55:59

US3512217

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Apr 2021 20:55:59

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 07:55:38

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:49:57
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:22:32

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:55:38

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:25:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:25:42
Data point term sent to Coder	System	04 Sep 2020 18:24:26
User entered 'lisinopril'	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:23:37

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:23:37

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'hypertension'	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:23:37

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered '20'	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:23:37

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'mg (mg)'	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:23:37

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered empty.	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:23:37

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'once daily (QD)'	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:23:37

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:55:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered empty.	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:23:37

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:55:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'Oral (ORAL)'	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:23:37

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:55:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered empty.	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:23:37

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:55:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'un UNK 2009'	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:23:37

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered '0'	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:23:37

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:23:37

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered empty.	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:23:37

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:23:37

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:55:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 18:23:37

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 18:23:37

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 18:23:37

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 18:26:46
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	04 Sep 2020 18:26:46
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	04 Sep 2020 18:25:27
User entered 'atorvastatin'	Taylor Johnson (b) (4)	04 Sep 2020 18:24:34
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:24:34

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'hypercholesterolemia'	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:24:34

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered '40'	Taylor Johnson (b) (4)	04 Sep 2020 18:24:34
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'mg (mg)'	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:24:34

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered empty.	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:24:34

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'once daily (QD)'	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:24:34

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:55:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered empty.	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:24:34

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:55:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'Oral (ORAL)'	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:24:34

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:55:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered empty.	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:24:34

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:55:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'un UNK 2010'	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:24:34

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered '0'	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:24:34

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:24:34

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered empty.	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:24:34

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:24:34

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:55:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 18:24:34

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 18:24:34

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 18:24:34

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:55:38

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 06:43:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 06:43:01
Data point term sent to Coder	System	12 Nov 2020 18:13:12
Coding entries removed.	Brenda Anderson (b) (4)	12 Nov 2020 18:12:27
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Sep 2020 05:41:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Sep 2020 05:41:49
Data point term sent to Coder	System	04 Sep 2020 18:25:30
User entered 'furosemides'	Taylor Johnson (b) (4)	04 Sep 2020 18:25:13

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'No (N)'	Taylor Johnson (b) (4)	04 Sep 2020 18:25:13
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 20:39:56
User closed query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH record that match this condition. Please update and ensure that there is a corresponding MH record that match the indication. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 03:51:11
Query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH record that match this condition. Please update and ensure that there is a corresponding MH record that match the indication. Otherwise, clarify. ' answered with 'matched # 11 of medical history' (Site from DM).	Brenda Anderson (b) (4)	12 Nov 2020 18:12:31
DataPoint Un-verified.	Brenda Anderson (b) (4)	12 Nov 2020 18:12:27
User entered 'BILATERAL LOWER LEG SWELLING' reason for change: New Information	Brenda Anderson (b) (4)	12 Nov 2020 18:12:27
User opened query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH record that match this condition. Please update and ensure that there is a corresponding MH record that match the indication. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:36:21
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'foot swelling'	Taylor Johnson (b) (4)	04 Sep 2020 18:25:13

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered '20'	Taylor Johnson (b) (4)	04 Sep 2020 18:25:13
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'mg (mg)'	Taylor Johnson (b) (4)	04 Sep 2020 18:25:13
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	06 Oct 2020 16:50:24
User entered empty.	Taylor Johnson (b) (4)	04 Sep 2020 18:25:13

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'once daily (QD)'	Taylor Johnson (b) (4)	04 Sep 2020 18:25:13
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:55:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered empty.	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:25:13

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:55:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'Oral (ORAL)'	Taylor Johnson (b) (4)	04 Sep 2020 18:25:13
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:55:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered empty.	Taylor Johnson (b) (4)	04 Sep 2020 18:25:13
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	06 Oct 2020 16:50:24
User entered 'un Jul 2020'	Taylor Johnson (b) (4)	04 Sep 2020 18:25:13

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	06 Oct 2020 16:50:24
User entered '0'	Taylor Johnson (b) (4)	04 Sep 2020 18:25:13

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Un-verified.	(b) (4)	
	Sheldon Warren (b) (4)	26 Feb 2021 20:07:06
Signature has been broken.	(b) (4)	
	Sheldon Warren (b) (4)	26 Feb 2021 20:07:06
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Sheldon Warren (b) (4)	26 Feb 2021 20:07:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'Yes (Y)'	Taylor Johnson (b) (4)	04 Sep 2020 18:25:13
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:55:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Un-verified.	(b) (4)	
	Sheldon Warren (b) (4)	26 Feb 2021 20:07:06
Signature has been broken.	(b) (4)	
	Sheldon Warren (b) (4)	26 Feb 2021 20:07:06
User entered '18 Feb 2021' reason for change: New Information	(b) (4)	
	Sheldon Warren (b) (4)	26 Feb 2021 20:07:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered empty.	Taylor Johnson (b) (4)	04 Sep 2020 18:25:13
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	06 Oct 2020 16:50:24
User entered 'No (N)'	Taylor Johnson (b) (4)	04 Sep 2020 18:25:13

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:55:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User entered '1'	System	04 Sep 2020 18:25:13

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User entered '1'	System	04 Sep 2020 18:25:13

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User entered '804 (804)'	System	04 Sep 2020 18:25:13

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:55:38

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:15
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS, PRODUCT: FINASTERIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 12:08:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	02 Mar 2021 12:08:42
Data point term sent to Coder	System	02 Mar 2021 12:07:55
Coding entries removed.	Allison Crain (b) (4)	02 Mar 2021 12:07:06
User signature succeeded.	(b) (4)	
	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS, PRODUCT: FINASTERIDE - version WHODrug-Global-B3\\202003.	(b) (4)	
	Coder Import (b) (4)	12 Nov 2020 22:08:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	12 Nov 2020 22:08:34
Data point term sent to Coder	System	12 Nov 2020 18:13:12
Coding entries removed.	Brenda Anderson (b) (4)	12 Nov 2020 18:13:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS, PRODUCT: FINASTERIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 18:41:37
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 18:41:37
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	04 Sep 2020 18:26:33
User entered 'finasteride'	Taylor Johnson (b) (4)	04 Sep 2020 18:25:56
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:15
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'No (N)'	Taylor Johnson (b) (4)	04 Sep 2020 18:25:56
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:15
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Un-verified.	(b) (4)	
	Allison Crain (b) (4)	02 Mar 2021 12:07:06
Signature has been broken.	(b) (4)	
	Allison Crain (b) (4)	02 Mar 2021 12:07:06
User entered 'BENIGN PROSTATIC HYPERPLASIA' reason for change: Data Entry Error	(b) (4)	
	Allison Crain (b) (4)	02 Mar 2021 12:07:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:39:56
User closed query 'Per DM CLR: Please review Indication and please update to specify the type of urination problem. Please update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 09:19:56
Query 'Per DM CLR: Please review Indication and please update to specify the type of urination problem. Please update as appropriate or provide clarification.' answered with 'corrected' (Site from DM).	Brenda Anderson (b) (4)	12 Nov 2020 18:13:18
	(b) (4)	
DataPoint Un-verified.	Brenda Anderson (b) (4)	12 Nov 2020 18:13:09
	(b) (4)	
User entered 'URINATION PROBLEMS decreased flow' reason for change: Data Entry Error	Brenda Anderson (b) (4)	12 Nov 2020 18:13:09
	(b) (4)	
User opened query 'Per DM CLR: Please review Indication and please update to specify the type of urination problem. Please update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 11:45:08
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'urination problems'	(b) (4)	
	Taylor Johnson (b) (4)	04 Sep 2020 18:25:56
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:15
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered '5'	Taylor Johnson (b) (4)	04 Sep 2020 18:25:56
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:15
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'mg (mg)'	Taylor Johnson (b) (4)	04 Sep 2020 18:25:56
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:55:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:15
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	06 Oct 2020 16:50:24
User entered empty.	Taylor Johnson (b) (4)	04 Sep 2020 18:25:56

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:15
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'once daily (QD)'	Taylor Johnson (b) (4)	04 Sep 2020 18:25:56
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:55:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:15
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered empty.	Taylor Johnson (b) (4)	04 Sep 2020 18:25:56
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:55:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:15
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'Oral (ORAL)'	Taylor Johnson (b) (4)	04 Sep 2020 18:25:56
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:55:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:15
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered empty.	Taylor Johnson (b) (4)	04 Sep 2020 18:25:56
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:55:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:15
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:39:56
User closed query 'Per DM CLR: Please review the start date of this medication as it was noted as prior to the start date of the corresponding MH condition. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Please review the start date of this medication as it was noted as prior to the start date of the corresponding MH condition. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 09:18:28
DataPoint Un-verified.	Brenda Anderson (b) (4) (b) (4)	12 Nov 2020 18:16:32
User entered 'UN Jul 2020' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	12 Nov 2020 18:16:25
User opened query 'Per DM CLR: Please review the start date of this medication as it was noted as prior to the start date of the corresponding MH condition. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:35:49
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'un Jan 2020'	Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:25:56

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:15
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered '0'	Taylor Johnson (b) (4)	04 Sep 2020 18:25:56
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:15
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Un-verified.	(b) (4)	
	Sheldon Warren (b) (4)	26 Feb 2021 20:07:38
Signature has been broken.	(b) (4)	
	Sheldon Warren (b) (4)	26 Feb 2021 20:07:38
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Sheldon Warren (b) (4)	26 Feb 2021 20:07:38
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'Yes (Y)'	Taylor Johnson (b) (4)	04 Sep 2020 18:25:56
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:55:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:15
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Un-verified.	(b) (4)	
	Sheldon Warren (b) (4)	26 Feb 2021 20:07:38
Signature has been broken.	(b) (4)	
	Sheldon Warren (b) (4)	26 Feb 2021 20:07:38
User entered '18 Feb 2021' reason for change: New Information	(b) (4)	
	Sheldon Warren (b) (4)	26 Feb 2021 20:07:38
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered empty.	Taylor Johnson (b) (4)	04 Sep 2020 18:25:56
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:15
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'No (N)'	Taylor Johnson (b) (4)	04 Sep 2020 18:25:56
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:55:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:15
User entered '1'	System	04 Sep 2020 18:25:56

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:15
User entered '1'	System	04 Sep 2020 18:25:56

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:15
User entered '804 (804)'	System	04 Sep 2020 18:25:56

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: NIFEDIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 12:08:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 12:08:42
Data point term sent to Coder Coding entries removed.	System Allison Crain (b) (4) (b) (4)	02 Mar 2021 12:07:55 02 Mar 2021 12:07:48
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: NIFEDIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 09:42:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 09:42:52
Data point term sent to Coder User entered 'Nifedipine'	System Taylor Johnson (b) (4) (b) (4)	04 Sep 2020 18:26:36 04 Sep 2020 18:26:34

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:31
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'No (N)'	Taylor Johnson (b) (4)	04 Sep 2020 18:26:34
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
DataPoint Un-verified.	(b) (4)	
	Allison Crain (b) (4)	02 Mar 2021 12:07:48
Signature has been broken.	(b) (4)	
	Allison Crain (b) (4)	02 Mar 2021 12:07:48
User entered 'HYPERTENSION' reason for change:	(b) (4)	
Data Entry Error	Allison Crain (b) (4)	02 Mar 2021 12:07:48
User signature succeeded.	(b) (4)	
	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'hypertensipon'	(b) (4)	
	Taylor Johnson (b) (4)	04 Sep 2020 18:26:34
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:31
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered '90'	Taylor Johnson (b) (4)	04 Sep 2020 18:26:34
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:31
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'mg (mg)'	Taylor Johnson (b) (4)	04 Sep 2020 18:26:34
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:55:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:31
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered empty.	Taylor Johnson (b) (4)	04 Sep 2020 18:26:34
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:31
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'once daily (QD)'	Taylor Johnson (b) (4)	04 Sep 2020 18:26:34
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:55:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:31
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	06 Oct 2020 16:50:24
User entered empty.	Taylor Johnson (b) (4)	04 Sep 2020 18:26:34

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:55:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:31
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'Oral (ORAL)'	Taylor Johnson (b) (4)	04 Sep 2020 18:26:34
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:55:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:31
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered empty.	Taylor Johnson (b) (4)	04 Sep 2020 18:26:34
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:31
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	06 Oct 2020 16:50:24
User entered 'un UNK 2009'	Taylor Johnson (b) (4)	04 Sep 2020 18:26:34

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:31
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered '0'	Taylor Johnson (b) (4)	04 Sep 2020 18:26:34
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:31
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	26 Jan 2021 20:39:56
DataPoint Un-verified.	Sheldon Warren (b) (4)	11 Jan 2021 23:10:29
User entered 'No (N)' reason for change: Data Entry Error	Sheldon Warren (b) (4)	11 Jan 2021 23:10:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'Yes (Y)'	Taylor Johnson (b) (4)	04 Sep 2020 18:26:34

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:31
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	26 Jan 2021 20:39:56
DataPoint Un-verified.	Sheldon Warren (b) (4)	11 Jan 2021 23:10:29
User entered '4 Jan 2021' reason for change: Data Entry Error	Sheldon Warren (b) (4)	11 Jan 2021 23:10:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered empty.	Taylor Johnson (b) (4)	04 Sep 2020 18:26:34

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:31
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	06 Oct 2020 16:50:24
User entered 'No (N)'	Taylor Johnson (b) (4)	04 Sep 2020 18:26:34

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:55:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:31
User entered '1'	System	04 Sep 2020 18:26:34

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:31
User entered '1'	System	04 Sep 2020 18:26:34

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:31
User entered '804 (804)'	System	04 Sep 2020 18:26:34

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:55:38

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
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, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 15:16:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 15:16:33
Data point term sent to Coder	System	29 Sep 2020 14:36:49
User entered 'Advil liquid'	Sheldon Warren (b) (4) (b) (4)	29 Sep 2020 14:36:43

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	29 Sep 2020 14:36:43

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'Low back pain'	Sheldon Warren (b) (4)	29 Sep 2020 14:36:43
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered '200'	Sheldon Warren (b) (4) (b) (4)	29 Sep 2020 14:36:43

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'mg (mg)'	Sheldon Warren (b) (4)	29 Sep 2020 14:36:43
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered empty.	Sheldon Warren (b) (4)	29 Sep 2020 14:36:43
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'as needed (PRN)'	Sheldon Warren (b) (4)	29 Sep 2020 14:36:43
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:55:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered empty.	Sheldon Warren (b) (4) (b) (4)	29 Sep 2020 14:36:43

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:55:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'Oral (ORAL)'	Sheldon Warren (b) (4)	29 Sep 2020 14:36:43
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:55:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered empty.	Sheldon Warren (b) (4) (b) (4)	29 Sep 2020 14:36:43

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered '16 Sep 2020'	Sheldon Warren (b) (4)	29 Sep 2020 14:36:43
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered '0'	Sheldon Warren (b) (4) (b) (4)	29 Sep 2020 14:36:43

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	29 Sep 2020 14:36:43

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:55:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered '26 Sep 2020'	Sheldon Warren (b) (4) (b) (4)	29 Sep 2020 14:36:43

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:50:24
User entered 'No (N)'	Sheldon Warren (b) (4)	29 Sep 2020 14:36:43
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:55:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:41
User entered empty.	System	29 Sep 2020 14:36:43

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:41
User entered empty.	System	29 Sep 2020 14:36:43

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:41
User entered empty.	System	29 Sep 2020 14:36:43

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:46
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:39:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN NICOTINE DEPENDENCE, PRODUCT: BUPROPION - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Jan 2021 15:00:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Jan 2021 15:00:56
Data point term sent to Coder	System	11 Jan 2021 23:22:35
User entered 'bupropion XL'	Sheldon Warren (b) (4) (b) (4)	11 Jan 2021 23:21:42

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:46
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:39:56
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	11 Jan 2021 23:21:42

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:46
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:39:56
User entered 'smoking cessation'	Sheldon Warren (b) (4) (b) (4)	11 Jan 2021 23:21:42

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:46
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:39:56
User entered '150'	Sheldon Warren (b) (4) (b) (4)	11 Jan 2021 23:21:42

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:46
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:39:56
User entered 'mg (mg)'	Sheldon Warren (b) (4) (b) (4)	11 Jan 2021 23:21:42

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:46
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:39:56
User entered empty.	Sheldon Warren (b) (4) (b) (4)	11 Jan 2021 23:21:42

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:46
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:39:56
User entered 'once daily (QD)'	Sheldon Warren (b) (4)	11 Jan 2021 23:21:42
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:55:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:46
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:39:56
User entered empty.	Sheldon Warren (b) (4)	11 Jan 2021 23:21:42
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:55:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:46
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:39:56
User entered 'Oral (ORAL)'	Sheldon Warren (b) (4) (b) (4)	11 Jan 2021 23:21:42

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:55:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:46
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:39:56
User entered empty.	Sheldon Warren (b) (4) (b) (4)	11 Jan 2021 23:21:42

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:46
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:39:56
User entered '7 Jan 2021'	Sheldon Warren (b) (4) (b) (4)	11 Jan 2021 23:21:42

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:46
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:39:56
User entered '0'	Sheldon Warren (b) (4) (b) (4)	11 Jan 2021 23:21:42

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:46
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
DataPoint Un-verified.	(b) (4), (b) (6)	02 Apr 2021 15:31:46
Signature has been broken.	(b) (4), (b) (6)	02 Apr 2021 15:31:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Apr 2021 15:31:46
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 20:39:56
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	11 Jan 2021 23:21:42

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:55:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:46
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:31:46
Signature has been broken.	(b) (4), (b) (6)	02 Apr 2021 15:31:46
User entered '15 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Apr 2021 15:31:46
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:39:56
User entered empty.	Sheldon Warren (b) (4) (b) (4)	11 Jan 2021 23:21:42

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:46
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:39:56
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	11 Jan 2021 23:21:42

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:55:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:46
User entered '1'	System	11 Jan 2021 23:21:42

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:46
User entered '1'	System	11 Jan 2021 23:21:42

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:46
User entered '804 (804)'	System	11 Jan 2021 23:21:42

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
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)	17 Feb 2021 11:28:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Feb 2021 11:28:58
Data point term sent to Coder	System	16 Feb 2021 13:25:41
User entered 'INFLUENZA VACCINE'	Allison Crain (b) (4)	16 Feb 2021 13:25:27

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 13:25:27

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered 'SEASONAL FLU PROPHYLAXIS'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 13:25:27

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered '0.5'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 13:25:27

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered 'mL (mL)'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 13:25:27

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 13:25:27

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered 'once (ONCE)'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 13:25:27

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:55:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 13:25:27

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:55:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered 'Intramuscular (INTRAMUSCULAR)'	Allison Crain (b) (4)	16 Feb 2021 13:25:27

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:55:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 13:25:27

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered '4 Jan 2021'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 13:25:27

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered '0'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 13:25:27

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered 'No (N)'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 13:25:27

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered '4 Jan 2021'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 13:25:27

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered 'No (N)'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 13:25:27

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:55:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:51
User entered empty.	System	16 Feb 2021 13:25:27

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:51
User entered empty.	System	16 Feb 2021 13:25:27

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:51
User entered empty.	System	16 Feb 2021 13:25:27

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN SODIUM - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Feb 2021 22:38:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 22:38:41
Data point term sent to Coder	System	16 Feb 2021 15:05:54
User entered 'HEPARIN SODIUM'	Allison Crain (b) (4) (b) (4)	16 Feb 2021 15:05:46

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 15:05:46

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered 'DVT PROPHYLAXIS'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 15:05:46

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered '5000'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 15:05:46

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered 'Other (OTHER)'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 15:05:46

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered 'UNITS'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 15:05:46

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered 'once (ONCE)'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 15:05:46

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:55:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 15:05:46

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:55:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered 'Subcutaneous (SUBCUTANEOUS)'	Allison Crain (b) (4)	16 Feb 2021 15:05:46

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:55:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 15:05:46

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered '1 Jan 2021'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 15:05:46

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered '0'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 15:05:46

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered 'No (N)'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 15:05:46

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered '1 Jan 2021'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 15:05:46

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered 'No (N)'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 15:05:46

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:55:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:55
User entered empty.	System	16 Feb 2021 15:05:46

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:55
User entered empty.	System	16 Feb 2021 15:05:46

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:49:55
User entered empty.	System	16 Feb 2021 15:05:46

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:00
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 14:02:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 14:02:45
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 00:15:42
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 Mar 2021 00:15:42
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:26:20
Data point term sent to Coder	System	16 Feb 2021 15:07:56
User entered 'SODIUM CHLORIDE'	Allison Crain (b) (4) (b) (4)	16 Feb 2021 15:07:01

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:00
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered 'No (N)'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 15:07:01

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:00
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered 'SYNCOPAL EPISODE'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 15:07:01

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:00
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered '1000'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 15:07:01

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:00
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered 'mL (mL)'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 15:07:01

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:00
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 15:07:01

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:00
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered 'once (ONCE)'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 15:07:01

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:55:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:00
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 15:07:01

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:55:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:00
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Allison Crain (b) (4)	16 Feb 2021 15:07:01

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:55:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:00
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 15:07:01

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:00
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered '31 Dec 2020'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 15:07:01

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:00
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered '0'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 15:07:01

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:00
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered 'No (N)'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 15:07:01

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:00
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered '31 Dec 2020'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 15:07:01

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:00
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:19:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered 'No (N)'	(b) (4) Allison Crain (b) (4) (b) (4)	16 Feb 2021 15:07:01

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:55:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:00
User entered empty.	System	16 Feb 2021 15:07:01

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:00
User entered empty.	System	16 Feb 2021 15:07:01

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:00
User entered empty.	System	16 Feb 2021 15:07:01

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:09
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
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: ACETAMINOPHEN;HYDROCODONE BITARTRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:12:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:12:53
User signature succeeded.	Michael Koren (b) (4) (b) (4)	05 Mar 2021 22:43:41
Data point term sent to Coder	System	05 Mar 2021 18:00:33
Data point term sent to Coder	System	24 Feb 2021 13:07:56
User entered 'hydrocodone Bitartrate Acetaminophen'	Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 13:07:03

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:09
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Mar 2021 18:00:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 18:00:18
User entered 'No (N)' reason for change: Data Entry Error	Allison Crain (b) (4)	05 Mar 2021 18:00:18
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Feb 2021 13:07:03
User entered empty.	System	24 Feb 2021 13:07:03
	Brenda Anderson (b) (4)	24 Feb 2021 13:07:03
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:09
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Mar 2021 18:00:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 18:00:18
User entered 'NECK AND RIGHT SHOULDER INJURY' reason for change: Data Entry Error	Allison Crain (b) (4)	05 Mar 2021 18:00:18
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	24 Feb 2021 13:07:03
	Brenda Anderson (b) (4)	24 Feb 2021 13:07:03
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:09
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
Signature has been broken.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:43:48
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Apr 2021 15:43:48
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	05 Mar 2021 18:20:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 18:20:49
User entered 'UNK' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	05 Mar 2021 18:20:49
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 13:07:03
User entered empty.	Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 13:07:03

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:09
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	(b) (4) System	05 Mar 2021 18:21:28
User entered 'Other (OTHER)' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	05 Mar 2021 18:21:28
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 18:21:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 18:21:19
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	05 Mar 2021 18:21:19
User entered 'tablet (TABLET)' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	05 Mar 2021 18:21:19
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 13:07:03
User entered empty.	Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 13:07:03

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:09
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
Comment added "'Unit" per medical records'.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:44:34
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	02 Apr 2021 15:44:14
User entered 'Unit' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Apr 2021 15:44:14
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	02 Apr 2021 15:43:48
Signature has been broken.	(b) (4), (b) (6)	02 Apr 2021 15:43:48
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	02 Apr 2021 15:43:48
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered 'UNK' reason for change: Data Entry Error	(b) (4) Allison Crain (b) (4)	05 Mar 2021 18:21:19
User entered empty.	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 13:07:03

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:09
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
Signature has been broken.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:43:48
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Apr 2021 15:43:48
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	05 Mar 2021 18:21:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 18:21:19
User entered 'unknown (UNKNOWN)' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	05 Mar 2021 18:21:19
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 13:07:03
User entered empty.	Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 13:07:03

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:55:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:09
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered empty.	(b) (4) Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 13:07:03

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:55:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:09
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Mar 2021 18:00:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 18:00:18
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Allison Crain (b) (4)	05 Mar 2021 18:00:18
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Feb 2021 13:07:03
User entered empty.	System	24 Feb 2021 13:07:03
	Brenda Anderson (b) (4)	24 Feb 2021 13:07:03
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:55:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:09
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered empty.	(b) (4) Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 13:07:03

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:55:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:09
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered '31 Dec 2020'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 13:07:03

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:09
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered '0'	(b) (4) Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 13:07:03

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:09
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered 'No (N)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 13:07:03

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:55:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:09
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered '31 Dec 2020'	Brenda Anderson (b) (4)	24 Feb 2021 13:07:03

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:09
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered 'No (N)'	Brenda Anderson (b) (4)	24 Feb 2021 13:07:03

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:55:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:09
User entered empty.	System	24 Feb 2021 13:07:03

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:09
User entered empty.	System	24 Feb 2021 13:07:03

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:09
User entered empty.	System	24 Feb 2021 13:07:03

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:14
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN SODIUM - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Mar 2021 08:04:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 08:04:38
Data point term sent to Coder	System	24 Feb 2021 13:09:57
User entered 'heparin sodium'	Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 13:09:17

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:14
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered 'Yes (Y)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 13:09:17

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:14
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered 'prophylaxis deep vein thrombosis'	Brenda Anderson (b) (4)	24 Feb 2021 13:09:17

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:14
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered '5000'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 13:09:17

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:14
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered 'Other (OTHER)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 13:09:17

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:14
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered 'unit/ml'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 13:09:17

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:14
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Feb 2021 20:50:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Feb 2021 20:50:17
User entered 'once (ONCE)' reason for change: Data Sheldon Warren Entry Error	(b) (4)	26 Feb 2021 20:50:17
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 13:09:17
User entered empty.	Brenda Anderson (b) (4)	24 Feb 2021 13:09:17
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:14
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered empty.	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 13:09:17

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:14
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 13:09:17

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:14
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered empty.	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 13:09:17

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:14
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered '1 Jan 2021'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 13:09:17

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:14
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered '0'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 13:09:17

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:14
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered 'No (N)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 13:09:17

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:14
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered '1 Jan 2021'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 13:09:17

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:14
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered 'No (N)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 13:09:17

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:14
User entered empty.	System	24 Feb 2021 13:09:17

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:14
User entered empty.	System	24 Feb 2021 13:09:17

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:14
User entered empty.	System	24 Feb 2021 13:09:17

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
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: ERGOCALCIFEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 10:48:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 10:48:16
Data point term sent to Coder	System	26 Feb 2021 20:52:08
User entered 'ergocalciferol'	Sheldon Warren (b) (4)	26 Feb 2021 20:51:39

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	26 Feb 2021 20:51:39

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered 'low vitamin D prophylaxis'	Sheldon Warren (b) (4)	26 Feb 2021 20:51:39

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered '50000'	Sheldon Warren (b) (4)	26 Feb 2021 20:51:39

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for the dose recorded. Please update the unit appropriate to the dose recorded. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 06:07:24
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for the dose recorded. Please update the unit appropriate to the dose recorded. ' answered with 'changed per query' (Site from DM).	Brenda Anderson (b) (4)	05 Apr 2021 14:23:49
Signature has been broken.	(b) (4)	
User entered 'IU (IU)' reason for change: Per Query Resolution	Brenda Anderson (b) (4)	05 Apr 2021 14:23:20
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for the dose recorded. Please update the unit appropriate to the dose recorded. ' (Site from DM).	(b) (4)	
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 05:59:59
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 05:59:13
User signature succeeded.	Michael Koren (b) (4)	05 Apr 2021 05:59:09
Signature has been broken.	(b) (4)	
User entered 'ug (ug)' reason for change: Data Entry Error	Allison Crain (b) (4)	19 Mar 2021 20:44:48
User signature succeeded.	(b) (4)	
User entered 'Other (OTHER)'	Allison Crain (b) (4)	16 Mar 2021 12:55:31
	(b) (4)	
	Allison Crain (b) (4)	16 Mar 2021 12:55:31
	(b) (4)	
	Michael Koren (b) (4)	05 Mar 2021 22:43:41
	(b) (4)	
	Sheldon Warren (b) (4)	26 Feb 2021 20:51:39
	(b) (4)	

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:48
User closed query 'Per DM CLR: Please review and verify if the UNIT can be more appropriately recorded as UG as it is one of the pre-listed options. If yes, please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 05:04:00
Query 'Per DM CLR: Please review and verify if the UNIT can be more appropriately recorded as UG as it is one of the pre-listed options. If yes, please update accordingly. ' answered with 'updated' (Site from DM).	Allison Crain (b) (4) (b) (4)	16 Mar 2021 12:55:38
Signature has been broken.	Allison Crain (b) (4) (b) (4)	16 Mar 2021 12:55:31
User entered empty; reason for change Data Entry Error	Allison Crain (b) (4) (b) (4)	16 Mar 2021 12:55:31
User opened query 'Per DM CLR: Please review and verify if the UNIT can be more appropriately recorded as UG as it is one of the pre-listed options. If yes, please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:23:33
User signature succeeded.	Michael Koren (b) (4) (b) (4)	05 Mar 2021 22:43:41
User entered 'mcg'	Sheldon Warren (b) (4) (b) (4)	26 Feb 2021 20:51:39

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered 'every week (QS)'	Sheldon Warren (b) (4)	26 Feb 2021 20:51:39

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered empty.	Sheldon Warren (b) (4)	26 Feb 2021 20:51:39

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered 'Oral (ORAL)'	Sheldon Warren (b) (4)	26 Feb 2021 20:51:39

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered empty.	Sheldon Warren (b) (4)	26 Feb 2021 20:51:39

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered '18 Feb 2021'	Sheldon Warren (b) (4)	26 Feb 2021 20:51:39

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered '0'	Sheldon Warren (b) (4)	26 Feb 2021 20:51:39

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	26 Feb 2021 20:51:39

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered empty.	Sheldon Warren (b) (4)	26 Feb 2021 20:51:39

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:41
User entered 'No (N)'	Sheldon Warren (b) (4)	26 Feb 2021 20:51:39

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 20:51:39

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 20:51:39

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	26 Feb 2021 20:51:39

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:18
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN NICOTINE DEPENDENCE, PRODUCT: VARENICLINE TARTRATE, PRODUCTSYNONYM: CHANTIX - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Apr 2021 15:39:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Apr 2021 15:39:34
Data point term sent to Coder	System	02 Apr 2021 15:38:11
User entered 'Chantix'	(b) (4), (b) (6)	02 Apr 2021 15:37:13

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:18
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:37:13

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:18
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered 'Smoking Cessation'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:37:13

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:18
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered '.5'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:37:13

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:18
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:37:13

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:18
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:37:13

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:18
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:37:13

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:18
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:37:13

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:18
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:37:13

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:18
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:37:13

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:18
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	02 Apr 2021 15:37:27
User entered '19 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Apr 2021 15:37:27
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	02 Apr 2021 15:37:13
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 15:37:13

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:18
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:37:13

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:18
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:37:13

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:18
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:37:13

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:18
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:37:13

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:18
User entered '1'	System	02 Apr 2021 15:37:13

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:18
User entered '1'	System	02 Apr 2021 15:37:13

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:50:18
User entered '804 (804)'	System	02 Apr 2021 15:37:13

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN NICOTINE DEPENDENCE, PRODUCT: VARENICLINE TARTRATE, PRODUCTSYNONYM: CHANTIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Apr 2021 15:39:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Apr 2021 15:39:35
Data point term sent to Coder	System	02 Apr 2021 15:38:11
User entered 'Chantix'	(b) (4), (b) (6)	02 Apr 2021 15:37:58

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:37:58

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered 'Smoking Cessation'	(b) (4), (b) (6)	02 Apr 2021 15:37:58

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered '.5'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:37:58

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:37:58

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:37:58

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:37:58

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:55:38

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:37:58

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:55:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:37:58

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:55:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:37:58

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:55:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:37:58

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:37:58

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Apr 2021 15:37:58

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 15:37:58

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:56:53
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:37:58

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:55:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Apr 2021 15:37:58

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Apr 2021 15:37:58

US3512217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Apr 2021 15:37:58

US3512217

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 07:55:38

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:36:51
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered 'No (N)'	Allison Crain (b) (4)	16 Feb 2021 12:22:15

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Query 'Please provide CRA with Safety Report form. ' canceled (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 20:36:43
User opened query 'Please provide CRA with Safety Report form. ' (Site from CRA).	(b) (4), (b) (6)	25 Jan 2021 19:50:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'USA-US065-2021-MRNA-1273-P301000001'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'Yes (Y)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'Yes (Y)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'Michael'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'Koren'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:23:53
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 20:36:47
User entered 'US'	System	06 Jan 2021 16:25:55

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	06 Apr 2021 18:11:52
User entered '5'	System	17 Mar 2021 14:45:35
User entered '4'	System	08 Mar 2021 16:02:36
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
	(b) (4)	
Signature has been broken.	System	17 Feb 2021 15:49:38
User entered '3'	System	17 Feb 2021 15:49:38
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
	(b) (4)	
User entered '2'	System	10 Feb 2021 16:23:30
User entered '1'	System	06 Jan 2021 16:25:55

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Query 'Please provide CRA with Safety Report form. ' canceled (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 20:36:43
User opened query 'Please provide CRA with Safety Report form. ' (Site from CRA).	(b) (4), (b) (6)	25 Jan 2021 19:50:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'USA-US065-2021-MRNA-1273-P301000001'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'Yes (Y)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'Yes (Y)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'Michael'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'Koren'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:23:53
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 20:36:47
User entered 'US'	System	06 Jan 2021 16:25:55

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	06 Apr 2021 18:11:52
User entered '5'	System	17 Mar 2021 14:45:35
User entered '4'	System	08 Mar 2021 16:02:36
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
	(b) (4)	
Signature has been broken.	System	17 Feb 2021 15:49:38
User entered '3'	System	17 Feb 2021 15:49:38
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
	(b) (4)	
User entered '2'	System	10 Feb 2021 16:23:30
User entered '1'	System	06 Jan 2021 16:25:55

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 07:55:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:36:47
User entered '06/Jan/2021 11:25'	System	06 Jan 2021 16:25:55

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 07:55:38

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.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 16:23:53
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 20:36:47
User entered 'I'	(b) (4), (b) (6)	06 Jan 2021 16:25:55

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Query 'Please provide CRA with Safety Report form. ' canceled (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 20:36:43
User opened query 'Please provide CRA with Safety Report form. ' (Site from CRA).	(b) (4), (b) (6)	25 Jan 2021 19:50:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'USA-US065-2021-MRNA-1273-P301000001'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'Yes (Y)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'Yes (Y)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'Michael'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'Koren'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:23:53
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 20:36:47
User entered 'US'	System	06 Jan 2021 16:25:55

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	06 Apr 2021 18:11:52
User entered '5'	System	17 Mar 2021 14:45:35
User entered '4'	System	08 Mar 2021 16:02:36
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
	(b) (4)	
Signature has been broken.	System	17 Feb 2021 15:49:38
User entered '3'	System	17 Feb 2021 15:49:38
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
	(b) (4)	
User entered '2'	System	10 Feb 2021 16:23:30
User entered '1'	System	06 Jan 2021 16:25:55

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 07:55:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:10:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
User entered '10/Feb/2021 11:23'	(b) (4) System	10 Feb 2021 16:23:30

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 07:55:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:10:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 16:23:53
User entered 'I'	(b) (4), (b) (6)	10 Feb 2021 16:23:30

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Query 'Please provide CRA with Safety Report form. ' canceled (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 20:36:43
User opened query 'Please provide CRA with Safety Report form. ' (Site from CRA).	(b) (4), (b) (6)	25 Jan 2021 19:50:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'USA-US065-2021-MRNA-1273-P301000001'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'Yes (Y)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

Death

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'Yes (Y)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'Michael'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'Koren'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:23:53
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 20:36:47
User entered 'US'	System	06 Jan 2021 16:25:55

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	06 Apr 2021 18:11:52
User entered '5'	System	17 Mar 2021 14:45:35
User entered '4'	System	08 Mar 2021 16:02:36
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
	(b) (4)	
Signature has been broken.	System	17 Feb 2021 15:49:38
User entered '3'	System	17 Feb 2021 15:49:38
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
	(b) (4)	
User entered '2'	System	10 Feb 2021 16:23:30
User entered '1'	System	06 Jan 2021 16:25:55

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 07:55:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:10:41
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
User entered '17/Feb/2021 09:49'	(b) (4) System	17 Feb 2021 15:49:38

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 07:55:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:10:41
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:49:42
User entered '1'	(b) (4), (b) (6)	17 Feb 2021 15:49:38

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Query 'Please provide CRA with Safety Report form. ' canceled (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 20:36:43
User opened query 'Please provide CRA with Safety Report form. ' (Site from CRA).	(b) (4), (b) (6)	25 Jan 2021 19:50:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'USA-US065-2021-MRNA-1273-P301000001'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'Yes (Y)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'Yes (Y)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'Michael'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'Koren'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:23:53
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 20:36:47
User entered 'US'	System	06 Jan 2021 16:25:55

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	06 Apr 2021 18:11:52
User entered '5'	System	17 Mar 2021 14:45:35
User entered '4'	System	08 Mar 2021 16:02:36
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
	(b) (4)	
Signature has been broken.	System	17 Feb 2021 15:49:38
User entered '3'	System	17 Feb 2021 15:49:38
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
	(b) (4)	
User entered '2'	System	10 Feb 2021 16:23:30
User entered '1'	System	06 Jan 2021 16:25:55

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 07:55:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:32:58
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:51:20
User entered '08/Mar/2021 11:02'	(b) (4) System	08 Mar 2021 16:02:36

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 07:55:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:11:33
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 15:33:00
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:51:20
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:02:36

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Query 'Please provide CRA with Safety Report form. ' canceled (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 20:36:43
User opened query 'Please provide CRA with Safety Report form. ' (Site from CRA).	(b) (4), (b) (6)	25 Jan 2021 19:50:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'USA-US065-2021-MRNA-1273-P301000001'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'Yes (Y)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'Yes (Y)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'Michael'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'Koren'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:23:53
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 20:36:47
User entered 'US'	System	06 Jan 2021 16:25:55

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	06 Apr 2021 18:11:52
User entered '5'	System	17 Mar 2021 14:45:35
User entered '4'	System	08 Mar 2021 16:02:36
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
	(b) (4)	
Signature has been broken.	System	17 Feb 2021 15:49:38
User entered '3'	System	17 Feb 2021 15:49:38
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
	(b) (4)	
User entered '2'	System	10 Feb 2021 16:23:30
User entered '1'	System	06 Jan 2021 16:25:55

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 07:55:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:10:41
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:48
User entered '17/Mar/2021 07:45'	(b) (4) System	17 Mar 2021 14:45:35

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 07:55:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:10:41
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:11:33
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:48
User entered 'I'	(b) (4), (b) (6)	17 Mar 2021 14:45:35

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Query 'Please provide CRA with Safety Report form. ' canceled (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 20:36:43
User opened query 'Please provide CRA with Safety Report form. ' (Site from CRA).	(b) (4), (b) (6)	25 Jan 2021 19:50:20
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'USA-US065-2021-MRNA-1273-P301000001'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'Yes (Y)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

Death

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'Yes (Y)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'No (N)'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'Michael'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:25:48
User entered 'Koren'	System	06 Jan 2021 16:25:32

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:23:53
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 20:36:47
User entered 'US'	System	06 Jan 2021 16:25:55

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	06 Apr 2021 18:11:52
User entered '5'	System	17 Mar 2021 14:45:35
User entered '4'	System	08 Mar 2021 16:02:36
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:26:20
	(b) (4)	
Signature has been broken.	System	17 Feb 2021 15:49:38
User entered '3'	System	17 Feb 2021 15:49:38
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:53:30
	(b) (4)	
User entered '2'	System	10 Feb 2021 16:23:30
User entered '1'	System	06 Jan 2021 16:25:55

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 07:55:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:10:41
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:10
User entered '06/Apr/2021 14:11'	(b) (4) System	06 Apr 2021 18:11:52

US3512217

Folder: SAE USA-US065-2021-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 07:55:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:10:41
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:10
User entered 'I'	(b) (4), (b) (6)	06 Apr 2021 18:11:52