

US3552191 (Prod: Saint Louis University)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:36:39

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US3552191

Form: Participant Creation

Generated On: 26 Nov 2020 09:36:39

[Participant ID](#)

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

US3552191

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:36:39

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	26 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:39

Date of Birth (MMM yyyy)	(b) (6) 1953
Age	66
Age Units	YEARS
Age (Derived)	66
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:36:39

Date of Informed Consent (<i>dd MMM yyyy</i>)	26 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☐
	Amendment 3 ☒
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:36:39

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:36:39

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:36:39

Condition	DIABETES MELLITUS TYPE 2
Start date (dd MMM yyyy)	UN JUN 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:36:39

Condition	MENIERE'S DISEASE
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:36:39

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:36:39

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:36:39

Condition	OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 1987
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1987
Start Year (derived)	1987
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:36:39

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

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:36:39

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

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:36:39

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:36:39

Condition	ROSACEA
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:36:39

Condition	BREAST CANCER
Start date (dd MMM yyyy)	UN JAN 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN JAN 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:36:39

Condition	MEDICATION ALLERGY: TOLECTIN
Start date (dd MMM yyyy)	UN UNK 1987
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1987
Start Year (derived)	1987
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:36:39

Condition	HERNIATED DISC
Start date (dd MMM yyyy)	UN UNK 1987
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1987
Start Year (derived)	1987
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:36:39

Condition	MENOPAUSE
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:36:39

Condition	LEFT HEEL ACHILLES TENDONITIS
Start date (dd MMM yyyy)	UN MAR 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:36:39

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

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Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:36:39

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

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	26 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	13:00 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 13:00
Height (<i>xxx.x</i>)	65 in
Weight (<i>xxx.x</i>)	171.2 lb
BMI (<i>xxx.x</i>)	28.54874 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:36:39

Date of assessment (<i>dd MMM yyyy</i>)	26 AUG 2020
Is the participant of childbearing potential?	Yes ☐
	No ☒
If No, what is the reason?	Surgically sterile ☐
	Post-menopausal ☒
	Partner medically sterile ☐
	Not reached age of Menarche ☐
	Other ☐
If Partner medically sterile or Other, specify _____	
If Surgically sterile, date of surgery (<i>dd MMM yyyy</i>) _____	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)	UN UNK 2003
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:39

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

BABYSITS GRANDCHILDREN (AGES 9, 5, AND TWO ARE 3 YEARS OLD) 1 - 3 TIMES A WEEK, GROCERY SHOPPING TWICE A WEEK, ATTENDS CHURCH SERVICES WEEKLY, WEARS MASK WHEN OUT.

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:39

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:36:39

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	26 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:36:39

What was the date of randomization? (dd MMM yyyy) 26 AUG 2020

What was the participant's randomization number? 188537

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

Generated On: 26 Nov 2020 09:36:39

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:39

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	13:00 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 13:00
Temperature (xxx.x)	97.6 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:39

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	15:50 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 15:50
Temperature (xxx.x)	97.9 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:39

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

Generated On: 26 Nov 2020 09:36:39

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 26 AUG 2020

What was the treatment time? (00:00-23:59) 15:20 (24 HR)

Treatment Date and Time (derived) 26 AUG 2020 15:20

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

Generated On: 26 Nov 2020 09:36:39

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	26 AUG 2020
Collection time (<i>00:00-23:59</i>)	14:38 (24 HR)
Collection date and time (derived)	26 AUG 2020 14:38

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:36:39

Collection date (<i>dd MMM yyyy</i>)			26 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:45	26 AUG 2020 14:45
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:36:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

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

26 AUG 2020 15:59

PC Open Date & Time

26 AUG 2020 15:40

PC Close Date & Time

26 AUG 2020 18:10

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 11:04

PC Open Date & Time

26 AUG 2020 19:05

PC Close Date & Time

27 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:39

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

99.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 20:19

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:39

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

99.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 20:21

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:39

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

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 19:24

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:39

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

98.7 °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

30 AUG 2020 19:13

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:39

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

31 AUG 2020 19:56

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:39

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

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 19:39

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 15:59

PC Open Date & Time

26 AUG 2020 15:40

PC Close Date & Time

26 AUG 2020 18:10

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

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

27 AUG 2020 11:05

PC Open Date & Time

26 AUG 2020 19:05

PC Close Date & Time

27 AUG 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 20:19

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 20:21

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 19:25

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 19:13

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 19:57

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:39

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

01 SEP 2020 19:39

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 16:00
PC Open Date & Time	26 AUG 2020 15:40
PC Close Date & Time	26 AUG 2020 18:10

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 11:06
PC Open Date & Time	26 AUG 2020 19:05
PC Close Date & Time	27 AUG 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:39

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 ☒

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:39

Yes ☐	
PC Time stamp	27 AUG 2020 20:20
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:39

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 ☒

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:39

Yes ☐	
PC Time stamp	28 AUG 2020 20:22
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:39

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 ☒

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:39

Yes ☐	
PC Time stamp	29 AUG 2020 19:25
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:39

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 ☒

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:39

Yes ☐	
PC Time stamp	30 AUG 2020 19:14
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:39

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 ☒

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:39

Yes ☐	
PC Time stamp	31 AUG 2020 19:57
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:39

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 ☒

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:39

Yes ☐	
PC Time stamp	01 SEP 2020 19:39
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3552191

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

Was Contact Attempted?

Yes ☒

No ☐

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

02 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552191

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552191

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552191

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552191

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552191

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:36:39

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	23 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:39

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	23 SEP 2020
Time of assessment (00:00-23:59)	08:55 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 08:55
Temperature (xxx.x)	98.3 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:39

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	23 SEP 2020
Time of assessment (00:00-23:59)	10:04 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 10:04
Temperature (xxx.x)	98.4 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3552191

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 SEP 2020

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

US3552191

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:36:39

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)	23 SEP 2020
What was the treatment time? (00:00-23:59)	09:34 (24 HR)
Treatment Date and Time (derived)	23 SEP 2020 09:34
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

US3552191

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:39

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	23 SEP 2020
Collection time (<i>00:00-23:59</i>)	09:12 (24 HR)
Collection date and time (derived)	23 SEP 2020 09:12

US3552191

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:36:39

Collection date (dd MMM yyyy)			23 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:15	23 SEP 2020 09:15
Nasopharyngeal Swab 2	No		

US3552191

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 10:03

PC Open Date & Time

23 SEP 2020 09:54

PC Close Date & Time

23 SEP 2020 12:24

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

23 SEP 2020 18:25

PC Open Date & Time

23 SEP 2020 13:19

PC Close Date & Time

24 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:39

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

101.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 18:39

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:39

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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 18:58

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:39

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

98.7 °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

26 SEP 2020 19:43

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:39

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

98.1 °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

27 SEP 2020 18:45

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:39

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

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 20:14

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:39

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

29 SEP 2020 22:11

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

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

23 SEP 2020 10:03

PC Open Date & Time

23 SEP 2020 09:54

PC Close Date & Time

23 SEP 2020 12:24

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

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

23 SEP 2020 18:25

PC Open Date & Time

23 SEP 2020 13:19

PC Close Date & Time

24 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:39

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

24 SEP 2020 18:41

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:39

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

25 SEP 2020 18:58

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:39

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

26 SEP 2020 19:44

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:39

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

27 SEP 2020 18:46

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:39

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

28 SEP 2020 20:14

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:39

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

29 SEP 2020 22:12

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 10:04
PC Open Date & Time	23 SEP 2020 09:54
PC Close Date & Time	23 SEP 2020 12:24

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 18:26
PC Open Date & Time	23 SEP 2020 13:19
PC Close Date & Time	24 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:39

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 ☒

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:39

Yes ☐	
PC Time stamp	24 SEP 2020 18:42
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:39

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 ☒

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:39

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 ☒

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:39

Yes ☐	
PC Time stamp	26 SEP 2020 19:44
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:39

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 ☒

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:39

Yes ☐	
PC Time stamp	27 SEP 2020 18:46
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:39

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 ☒

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:39

Yes ☐	
PC Time stamp	28 SEP 2020 20:15
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:39

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 ☒

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:39

Yes ☐	
PC Time stamp	29 SEP 2020 22:12
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 30 SEP 2020 21:06

PC Open Date & Time 30 SEP 2020 12:00

PC Close Date & Time 01 OCT 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 01 OCT 2020 20:24

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	30 SEP 2020 21:06
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	01 OCT 2020 20:24
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3552191

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552191

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552191

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552191

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552191

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552191

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552191

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:36:39

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	19 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3552191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 OCT 2020

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

US3552191

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:39

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 OCT 2020

Collection time (00:00-23:59)

10:25 (24 HR)

Collection date and time (derived)

19 OCT 2020 10:25

US3552191

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Date and time of submission	26 OCT 2020 21:26:08
Patient Cloud Open Date & Time	26 OCT 2020 00:01
Patient Cloud Close Date & Time	30 OCT 2020 23:59

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 NOV 2020 22:08:49

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 NOV 2020 21:03:28
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2020 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2020 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2020 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

[Patient Cloud Open Date & Time](#)

13 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2020 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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	24 NOV 2020 09:55:56
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2020 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2020 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2020 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2020 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2020 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2021 00:01

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19 JAN 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2021 00:01

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26 JAN 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2021 00:01

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02 FEB 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

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05 FEB 2021 00:01

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09 FEB 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

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12 FEB 2021 00:01

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16 FEB 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

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23 FEB 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

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02 MAR 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

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09 MAR 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2021 00:01

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16 MAR 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

DAY 208

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2021 00:01

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23 MAR 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

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13 APR 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2021 00:01

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20 APR 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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01 FEB 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

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08 FEB 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

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11 FEB 2022 00:01

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15 FEB 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

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22 FEB 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT	DAY 551
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

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01 MAR 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

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US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

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15 MAR 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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22 MAR 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

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29 MAR 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

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05 APR 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

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15 APR 2022 00:01

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19 APR 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

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22 APR 2022 00:01

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26 APR 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

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03 MAY 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

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06 MAY 2022 00:01

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10 MAY 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

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17 MAY 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

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20 MAY 2022 00:01

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24 MAY 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

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27 MAY 2022 00:01

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31 MAY 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

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03 JUN 2022 00:01

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07 JUN 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

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10 JUN 2022 00:01

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14 JUN 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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21 JUN 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

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24 JUN 2022 00:01

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28 JUN 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT	DAY 677
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

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05 JUL 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

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12 JUL 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

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19 JUL 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

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22 JUL 2022 00:01

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26 JUL 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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02 AUG 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3552191

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552191

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:39

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:36:39

Date of Contact	07 OCT 2020
Time of Contact	12:39
Date and Time of Contact (derived)	07 OCT 2020 12:39
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☒
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☒
	No ☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:36:39

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☒
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:36:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	02 OCT 2020	
Assessment Not Done	True	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	349 of 3055	

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:36:39

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:36:39

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:36:39

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☒
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:36:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	03 OCT 2020	
Assessment Not Done	True	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	353 of 3055	

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:36:39

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:36:39

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:36:39

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☒
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:36:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	04 OCT 2020	
Assessment Not Done	True	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	357 of 3055	

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:36:39

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:36:39

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:36:39

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☒
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:36:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	05 OCT 2020	
Assessment Not Done	True	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	361 of 3055	

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:36:39

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:36:39

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:36:39

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☒
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:36:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	06 OCT 2020	
Assessment Not Done	True	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	365 of 3055	

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:36:39

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:36:39

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:36:39

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☒
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:36:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	07 OCT 2020	
Assessment Not Done	True	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	369 of 3055	

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:36:39

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:36:39

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:36:39

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☒
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:36:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	08 OCT 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	373 of 3055	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:36:39

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:36:39

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:36:39

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☒
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:36:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	09 OCT 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	99 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	377 of 3055	

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:36:39

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:36:39

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:36:39

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☒
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:36:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	10 OCT 2020	
Assessment Not Done	True	
O2 Saturation	88 %	
O2 Saturation Units	%	
Temperature	98 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	381 of 3055	

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:36:39

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:36:39

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:36:39

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☒
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:36:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	11 OCT 2020	
Assessment Not Done	False	
O2 Saturation	91 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	385 of 3055	

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:36:39

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:36:39

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:36:39

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☒
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:36:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	12 OCT 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	389 of 3055	

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:36:39

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:36:39

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:36:39

Symptom Day

Day 1	☒
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:36:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	30 SEP 2020	
Assessment Not Done	True	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	393 of 3055	

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:36:39

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:36:39

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:36:39

[Symptom Day](#)

Day 1	☐
Day 2	☒
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:36:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	01 OCT 2020	
Assessment Not Done	True	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	397 of 3055	

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:36:39

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:36:39

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:36:39

Date of Visit	8 OCT 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ☒ No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ☐ No ☒
Date of Test	8 OCT 2020
Type of Test Performed	Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐
Other, specify _____	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☐ No ☒
If yes, provide lab information below	
Lab/ Institution Test Performed	_____
CLIA Certified?	Yes ☐ No ☐
COVID-19 Positive (CSA Programming Field Only)	0

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:36:39

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3552191

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 09:36:39

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	09 OCT 2020
Day 5	Yes	12 OCT 2020
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3552191

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:36:39

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	08 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☒
	Clinic ☐
Folder OID	SICKD1

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	08 OCT 2020
Time of assessment (00:00-23:59)	08:30 (24 HR)
Vital Signs Date and Time (derived)	08 OCT 2020 08:30
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.3 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	111 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:39

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: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:36:39

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

08 OCT 2020

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Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:36:39

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

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

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Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:39

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: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:36:39

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

US3552191

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:36:39

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

AEID	
Adverse event	FATIGUE
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)	24 SEP 2020
Start time (00:00-23:59)	18:42 (24 HR)
AE start date and time (derived)	24 SEP 2020 18:42
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False
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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

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

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:36:39

AEID	USA-US089-2020-MRNA-1273-P30 1000009
Adverse event	BILATERAL ANKLE EDEMA
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)	06 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	31 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	09 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	10 OCT 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:36:39

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

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:36:39

SUBJECT NOTIFIED SITE
07OCT2020 OF SHORTNESS OF
BREATH ON EXERTION,
FATIGUE AND SWOLLEN
ANKLES. SITE SENT HOME
HEALTH NURSES TO HER HOME
ON 08OCT2020 TO DO ILLNESS
VISIT AND ADVISED HER TO
NOTIFY HER PCP OF
SYMPTOMS. SUBJECT SAW PCP
ON 09OCT2020 AND WAS SENT
TO ER FOR CARDIAC
EVALUATION. WAS ADMITTED
OVERNIGHT TO HOSPITAL AND
TREATED WITH IVP LASIX AND
DIURESED. HAD LAB WORK,
ECG AND CT OF CHEST.
DISCHARGED THE NEXT DAY
AND HAD ECHOCARDIOGRAM
THE AM OF 12OCT2020.
HOSPITAL MEDICAL RECORDS
RECEIVED AND SENT TO
SPONSOR. PER
CARDIOLOGIST'S OFFICE, ECHO
NEGATIVE. X RAY "WITHOUT
SIGNIFICANT OR ACUTE
FINDINGS," CHEST CT "NO
EVIDENCE OF PE," ECG "SINUS
TACHYCARDIA, NO EVIDENCE
OF INJURY PATTERN"; PCP
PRESCRIBED ATENOLOL FOR
SUBJECT, STARTED ON
30OCT2020. AS OF 11/18 PHONE
CALL, SUBJECT REPORTS THAT
IT HAS RESOLVED.

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

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

AEID	
Adverse event	COUGH
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)	08 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	08 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

AEID	
Adverse event	HEADACHE
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)	08 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	08 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False
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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

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

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

AEID	
Adverse event	SORE THROAT
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)	08 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	08 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

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

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:36:39

AEID	USA-US089-2020-MRNA-1273-P30 1000009
Adverse event	SHORTNESS OF BREATH ON EXERTION
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)	30 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	09 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	10 OCT 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:36:39

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

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:36:39

SUBJECT NOTIFIED SITE
07OCT2020 OF SHORTNESS OF
BREATH ON EXERTION,
FATIGUE AND SWOLLEN
ANKLES. SITE SENT HOME
HEALTH NURSES TO HER HOME
ON 08OCT2020 TO DO ILLNESS
VISIT AND ADVISED HER TO
NOTIFY HER PCP OF
SYMPTOMS. SUBJECT SAW PCP
ON 09OCT2020 AND WAS SENT
TO ER FOR CARDIAC
EVALUATION. WAS ADMITTED
OVERNIGHT TO HOSPITAL AND
TREATED WITH IVP LASIX AND
DIURESED. HAD LAB WORK,
ECG AND CT OF CHEST.
DISCHARGED THE NEXT DAY
AND HAD ECHOCARDIOGRAM
THE AM OF 12OCT2020.
HOSPITAL MEDICAL RECORDS
RECEIVED AND SENT TO
SPONSOR. PER
CARDIOLOGIST'S OFFICE, ECHO
NEGATIVE. X RAY "WITHOUT
SIGNIFICANT OR ACUTE
FINDINGS," CHEST CT "NO
EVIDENCE OF PE," ECG "SINUS
TACHYCARDIA, NO EVIDENCE
OF INJURY PATTERN."

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

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:36:39

AEID	
Adverse event	ANEMIA
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	09 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	20 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False
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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:36:39

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

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

AEID	
Adverse event	SINUS TACHYCARDIA
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	09 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	09 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

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

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

AEID	
Adverse event	MUSCLE WEAKNESS
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	09 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

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

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

AEID	
Adverse event	HYPERTHYROIDISM
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)	26 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

AEID	
Adverse event	ITCHING
Was this a medically-attended AE?	Yes ☐ No ☒
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	09 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:36:39

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

Yes ☒

No ☐

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

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:39

Name of Medication	METFORMIN
Prophylaxis	Yes ☐ No ☒
Indication	TYPE 2 DIABETES MELLITUS
Dose per administration	500
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:39

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN JUN 2018
Start date completely unknown	False
Ongoing?	Yes ☒
	No ☐
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:39

Name of Medication	HCTZ / TRIAMTERENE
Prophylaxis	Yes ☐ No ☒
Indication	MENIERE'S DISEASE
Dose per administration	25 / 37.5
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:39

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:39

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 ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:39

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:39

Name of Medication	VENLAFAXINE
Prophylaxis	Yes ☐ No ☒
Indication	MILD DEPRESSION
Dose per administration	75
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:39

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1990
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:39

Name of Medication	VITAMIN B12
Prophylaxis	Yes ☐ No ☒
Indication	REPLACEMENT FOR OR PREVENTATIVE OF METFORMIN DEPLETION
Dose per administration	1000
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:39

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUN 2018	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:39

Name of Medication	GABAPENTIN
Prophylaxis	Yes ☐ No ☒
Indication	OSTEOARTHRITIS
Dose per administration	300
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:39

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2016
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:39

Name of Medication	VITAMIN D3
Prophylaxis	Yes ☐ No ☒
Indication	VITAMIN D DEFICIENCY
Dose per administration	50
Dose unit	mg ☐ ug ☒ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:39

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2012
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:39

Name of Medication	CENTRUM SILVER
Prophylaxis	Yes ☒ No ☐
Indication	HEALTH PROMOTION
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☒ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:39

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:39

Name of Medication	MAGNESIUM CITRATE
Prophylaxis	Yes ☐ No ☒
Indication	CONSTIPATION
Dose per administration	250
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:39

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

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:39

Name of Medication	CETIRIZINE
Prophylaxis	Yes ☐ No ☒
Indication	SEASONAL ALLERGIES
Dose per administration	10
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:39

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2017
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:39

Name of Medication	LASIX
Prophylaxis	Yes ☐ No ☒
Indication	SHORTNESS OF BREATH AND BILATERAL LOWER LEG EDEMA
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 ☐

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:39

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	09 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		09 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:39

Name of Medication	COREG
Prophylaxis	Yes ☐ No ☒
Indication	TACHYCARDIA
Dose per administration	6.25
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:39

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		26 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:39

Name of Medication	METHIMAZOLE
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTHYROIDISM
Dose per administration	30
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:39

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	26 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:39

Name of Medication	ATENOLOL
Prophylaxis	Yes ☐ No ☒
Indication	TACHYCARDIA
Dose per administration	25
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:39

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		30 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		09 NOV 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:39

Name of Medication	METHIMAZOLE
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTHYROIDISM
Dose per administration	30
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:39

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	26 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	09 NOV 2020	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:36:39

Name of Medication	ATENOLOL
Prophylaxis	Yes ☐ No ☒
Indication	TACHYCARDIA
Dose per administration	50
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:36:39

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		09 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:36:39

Name of Medication	METHIMAZOLE
Prophylaxis	Yes ☐ No ☒
Indication	HYERTHYROIDISM
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 ☐ Intramuscular ☐

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:36:39

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		09 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:36:39

Name of Medication	BENADRYL
Prophylaxis	Yes ☐ No ☒
Indication	ITCHING
Dose per administration	25
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:36:39

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		09 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:36:39

Name of Medication	INFLUENZA VACCINE
Prophylaxis	Yes ☒ No ☐
Indication	INFLUENZA PROPHYLAXIS
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	INJECTION
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☒

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:36:39

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		30 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		30 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3552191

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:36:39

[Were any concomitant procedures performed?](#)

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3552191

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:36:39

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3552191

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:36:39

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 ☐

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

SAEID	USA-US089-2020-MRNA-1273-P301000009
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:36:39

SAEID	USA-US089-2020-MRNA-1273-P301000009
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	12/OCT/2020 08:43
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:36:39

SAEID	USA-US089-2020-MRNA-1273-P301000009
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	13/OCT/2020 13:30
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

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:36:39

SAEID	USA-US089-2020-MRNA-1273-P301000009
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	13/OCT/2020 15:24
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

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:36:39

SAEID	USA-US089-2020-MRNA-1273-P301000009
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	15/OCT/2020 08:28
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

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:36:39

SAEID	USA-US089-2020-MRNA-1273-P301000009
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	15/OCT/2020 08:44
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

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 09:36:39

SAEID	USA-US089-2020-MRNA-1273-P301000009
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	15/OCT/2020 20:20
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

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (7)

Generated On: 26 Nov 2020 09:36:39

SAEID	USA-US089-2020-MRNA-1273-P301000009
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	22/OCT/2020 17:23
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

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (8)

Generated On: 26 Nov 2020 09:36:39

SAEID	USA-US089-2020-MRNA-1273-P301000009
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	26/OCT/2020 13:05
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

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (9)

Generated On: 26 Nov 2020 09:36:39

SAEID	USA-US089-2020-MRNA-1273-P301000009
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	29/OCT/2020 11:07
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

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (10)

Generated On: 26 Nov 2020 09:36:39

SAEID	USA-US089-2020-MRNA-1273-P301000009
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	10/NOV/2020 19:08
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (11)

Generated On: 26 Nov 2020 09:36:39

SAEID	USA-US089-2020-MRNA-1273-P301000009
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	12/NOV/2020 14:28
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

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (12)

Generated On: 26 Nov 2020 09:36:39

SAEID	USA-US089-2020-MRNA-1273-P301000009
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	20/NOV/2020 21:48
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

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (13)

Generated On: 26 Nov 2020 09:36:39

SAEID	USA-US089-2020-MRNA-1273-P301000009
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	23/NOV/2020 21:55
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

US3552191 (Prod: Saint Louis University)

US3552191

Form: Participant Creation

Generated On: 26 Nov 2020 09:36:39

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3552191'	RWS_ENDPOINT ENDPOINT (b) (4) 	26 Aug 2020 19:50:32

US3552191

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:36:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:51:05

US3552191

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '26 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	26 Aug 2020 19:50:33

US3552191

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:51:05

US3552191

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:36:39

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	27 Aug 2020 14:51:05

US3552191

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered (b) (6) 1953'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	26 Aug 2020 19:50:34

US3552191

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:39

[Age](#)

Audit	User	Time (GMT)
User entered '66'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:51:26

US3552191

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:39

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	27 Aug 2020 14:51:26

US3552191

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:39

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '66'	System	26 Aug 2020 19:58:47

US3552191

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:39

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:51:26

US3552191

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:39

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:51:26

US3552191

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:39

White

Audit	User	Time (GMT)
User entered '1'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:51:26

US3552191

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:39

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:51:26

US3552191

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:39

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:51:26

US3552191

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:39

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:51:26

US3552191

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:39

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:51:26

US3552191

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:39

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:51:26

US3552191

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:39

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:51:26

US3552191

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:39

Unknown

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:51:26

US3552191

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:39

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:51:26

US3552191

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '26 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 19:58:47

US3552191

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	26 Aug 2020 19:58:47

US3552191

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '2020'	System	26 Aug 2020 19:58:47

US3552191

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:36:39

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	26 Aug 2020 19:58:47

US3552191

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 19:58:47

US3552191

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 19:58:47

US3552191

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:36:39

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 19:58:47

US3552191

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:36:39

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 19:58:47

US3552191

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:36:39

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	26 Aug 2020 19:50:33

US3552191

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:36:39

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 19:58:54

US3552191

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 19:58:54

US3552191

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:36:39

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:51:50

US3552191

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:36:39

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:38:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:38:10
Data point term sent to Coder	System	27 Aug 2020 16:47:21
User entered 'DIABETES MELLiTUS type 2' reason for change: Data Entry Error	Joan Siegner (b) (4) (b) (4)	27 Aug 2020 16:47:20
Data point term sent to Coder	System	27 Aug 2020 14:52:30
User entered 'diabetes mellitus'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:52:14

US3552191

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'un Jun 2018'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:52:14

US3552191

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:52:14

US3552191

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:36:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:52:14

US3552191

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:52:14

US3552191

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:36:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:52:14

US3552191

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'Jun 2018'	System	27 Aug 2020 14:52:14

US3552191

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '2018'	System	27 Aug 2020 14:52:14

US3552191

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 14:52:14

US3552191

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 14:52:14

US3552191

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:36:39

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear disorders NEC, PT: Meniere's disease, LLT: Meniere's disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:21:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:21:42
Data point term sent to Coder	System	27 Aug 2020 14:53:31
User entered 'meniere's disease'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:52:46

US3552191

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'un UNK 2015'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:52:46

US3552191

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:52:46

US3552191

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:36:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:52:46

US3552191

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:52:46

US3552191

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:36:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:52:46

US3552191

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	27 Aug 2020 14:52:46

US3552191

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '2015'	System	27 Aug 2020 14:52:46

US3552191

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 14:52:46

US3552191

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 14:52:46

US3552191

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:36:39

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
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.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:21:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:21:42
Data point term sent to Coder	System	27 Aug 2020 14:53:32
User entered 'hypercholesterolemia'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:53:12

US3552191

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'un UNK 2000'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:53:12

US3552191

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:53:12

US3552191

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:36:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:53:12

US3552191

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:53:12

US3552191

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:36:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:53:12

US3552191

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	27 Aug 2020 14:53:12

US3552191

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '2000'	System	27 Aug 2020 14:53:12

US3552191

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 14:53:12

US3552191

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 14:53:12

US3552191

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:36:39

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:21:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	27 Aug 2020 19:21:46
Data point term sent to Coder	System	27 Aug 2020 14:55:34
User entered 'depression'	Stanley Doublin (b) (4)	27 Aug 2020 14:54:39
	(b) (4)	

US3552191

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'un UNK 1990'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:54:39

US3552191

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:54:39

US3552191

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:36:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:54:39

US3552191

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:54:39

US3552191

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:36:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:54:39

US3552191

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	27 Aug 2020 14:54:39

US3552191

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '1990'	System	27 Aug 2020 14:54:39

US3552191

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 14:54:39

US3552191

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 14:54:39

US3552191

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:36:39

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:22:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:22:22
Data point term sent to Coder	System	27 Aug 2020 14:57:35
User entered 'osteoarthritis'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:56:50

US3552191

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'un UNK 1987'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:56:50

US3552191

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:56:50

US3552191

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:36:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:56:50

US3552191

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:56:50

US3552191

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:36:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:56:50

US3552191

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'Jan 1987'	System	27 Aug 2020 14:56:50

US3552191

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '1987'	System	27 Aug 2020 14:56:50

US3552191

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 14:56:50

US3552191

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 14:56:50

US3552191

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:36:39

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:22:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:22:21
Data point term sent to Coder	System	27 Aug 2020 14:57:36
User entered 'vitamin d deficiency'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:57:13

US3552191

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'un UNK 2012'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:57:13

US3552191

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:57:13

US3552191

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:36:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:57:13

US3552191

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:57:13

US3552191

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:36:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:57:13

US3552191

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	27 Aug 2020 14:57:13

US3552191

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '2012'	System	27 Aug 2020 14:57:13

US3552191

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 14:57:13

US3552191

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 14:57:13

US3552191

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:36:39

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:22:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:22:21
Data point term sent to Coder	System	27 Aug 2020 14:57:36
User entered 'constipation'	Stanley Doublin (b) (4)	27 Aug 2020 14:57:34
	(b) (4)	

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'un UNK 2019'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:57:34

US3552191

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:57:34

US3552191

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:36:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:57:34

US3552191

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:57:34

US3552191

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:36:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:57:34

US3552191

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	27 Aug 2020 14:57:34

US3552191

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '2019'	System	27 Aug 2020 14:57:34

US3552191

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 14:57:34

US3552191

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 14:57:34

US3552191

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:36:39

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:22:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:22:32
Data point term sent to Coder	System	27 Aug 2020 14:58:38
User entered 'seasonal allergies'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:57:47

US3552191

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'un UNK 2017'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:57:47

US3552191

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:57:47

US3552191

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:36:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:57:47

US3552191

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:57:47

US3552191

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:36:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:57:47

US3552191

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	27 Aug 2020 14:57:47

US3552191

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '2017'	System	27 Aug 2020 14:57:47

US3552191

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 14:57:47

US3552191

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 14:57:47

US3552191

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:36:39

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Rosaceas, PT: Rosacea, LLT: Rosacea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:22:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:22:31
Data point term sent to Coder	System	27 Aug 2020 14:58:37
User entered 'rosacea'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:58:02

US3552191

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'un UNK 1990'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:58:02

US3552191

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:58:02

US3552191

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:36:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:58:02

US3552191

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:58:02

US3552191

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:36:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:58:02

US3552191

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	27 Aug 2020 14:58:02

US3552191

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '1990'	System	27 Aug 2020 14:58:02

US3552191

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 14:58:02

US3552191

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 14:58:02

US3552191

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:36:39

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Breast cancer, LLT: Breast cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:38:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:38:17
Data point term sent to Coder	System	27 Aug 2020 16:48:24
User entered 'BREAST CANCER' reason for change: Data Entry Error	Joan Siegner (b) (4) (b) (4)	27 Aug 2020 16:47:47
Data point term sent to Coder	System	27 Aug 2020 14:59:42
User entered 'breast cancer (Right)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:58:53

US3552191

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'un Jan 2007'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:58:53

US3552191

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:58:53

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:36:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:58:53

US3552191

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'un Jan 2012'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:58:53

US3552191

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:36:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:58:53

US3552191

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'Jan 2007'	System	27 Aug 2020 14:58:53

US3552191

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '2007'	System	27 Aug 2020 14:58:53

US3552191

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	27 Aug 2020 14:58:53

US3552191

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '2012'	System	27 Aug 2020 14:58:53

US3552191

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:36:39

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 22:01:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 22:01:36
Data point term sent to Coder	System	27 Aug 2020 15:00:43
User entered 'medication allergy: tolectin'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:59:47

US3552191

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'un UNK 1987'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:59:47

US3552191

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:59:47

US3552191

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:36:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:59:47

US3552191

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:59:47

US3552191

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:36:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:59:47

US3552191

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'Jan 1987'	System	27 Aug 2020 14:59:47

US3552191

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '1987'	System	27 Aug 2020 14:59:47

US3552191

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 14:59:47

US3552191

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 14:59:47

US3552191

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:36:39

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Herniated disc - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:23:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:23:10
Data point term sent to Coder	System	27 Aug 2020 15:00:43
User entered 'herniated disc'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:00:28

US3552191

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'un UNK 1987'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:00:28

US3552191

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:00:28

US3552191

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:36:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 15:00:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 15:00:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	27 Aug 2020 15:00:33
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 15:00:28
User entered empty.	Stanley Doublin (b) (4)	27 Aug 2020 15:00:28

US3552191

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:00:28

US3552191

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:36:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:00:28

US3552191

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'Jan 1987'	System	27 Aug 2020 15:00:28

US3552191

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '1987'	System	27 Aug 2020 15:00:28

US3552191

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 15:00:28

US3552191

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 15:00:28

US3552191

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:36:39

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 16:10:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 16:10:46
Data point term sent to Coder	System	03 Oct 2020 16:10:20
User entered 'menopause'	Joan Siegner (b) (4)	03 Oct 2020 16:09:33

US3552191

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'un UNK 2003'	Joan Siegner (b) (4)	03 Oct 2020 16:09:33

US3552191

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 16:09:33

US3552191

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:36:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'Yes (Y)'	Joan Siegner (b) (4)	03 Oct 2020 16:09:33

US3552191

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered empty.	Joan Siegner (b) (4)	03 Oct 2020 16:09:33

US3552191

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:36:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Joan Siegner (b) (4)	03 Oct 2020 16:09:33

US3552191

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'Jan 2003'	System	03 Oct 2020 16:09:33

US3552191

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '2003'	System	03 Oct 2020 16:09:33

US3552191

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	03 Oct 2020 16:09:33

US3552191

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	03 Oct 2020 16:09:33

US3552191

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:36:39

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Tendon, ligament and cartilage disorders, HLT: Tendon disorders, PT: Tendonitis, LLT: Achilles tendonitis - version MedDRA\23.0.	Coder Import (b) (4)	19 Nov 2020 23:59:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	19 Nov 2020 23:59:49
Data point term sent to Coder	System	19 Nov 2020 13:43:25
DataPoint Un-verified.	Stanley Doublin (b) (4)	19 Nov 2020 13:42:33
Coding entries removed.	(b) (4)	
	Stanley Doublin (b) (4)	19 Nov 2020 13:42:33
	(b) (4)	
User entered 'left heel ACHILLES TENDONITIS' reason for change: Data Entry Error	Stanley Doublin (b) (4)	19 Nov 2020 13:42:33
User closed query 'Per DM CLR: Please specify the location (bilateral, left, right) of ACHILLES TENDONITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please specify the location (bilateral, left, right) of ACHILLES TENDONITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'unknown at this time' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:14:21
Query 'Per DM CLR: Please specify the location (bilateral, left, right) of ACHILLES TENDONITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'unknown at this time' (Site from DM).	Joan Siegner (b) (4)	26 Oct 2020 15:33:37
User opened query 'Per DM CLR: Please specify the location (bilateral, left, right) of ACHILLES TENDONITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 20:53:11
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Tendon, ligament and cartilage disorders, HLT: Tendon disorders, PT: Tendonitis, LLT: Achilles tendonitis - version MedDRA\23.0.	Coder Import (b) (4)	07 Oct 2020 19:56:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	07 Oct 2020 19:56:57

US3552191

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:36:39

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	07 Oct 2020 19:11:03
User entered 'achilles tendonitis'	Joan Siegner (b) (4)	07 Oct 2020 19:11:01

US3552191

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'un Mar 2020'	Joan Siegner (b) (4)	07 Oct 2020 19:11:01

US3552191

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Joan Siegner (b) (4)	07 Oct 2020 19:11:01

US3552191

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:36:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'Yes (Y)'	Joan Siegner (b) (4)	07 Oct 2020 19:11:01

US3552191

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered empty.	Joan Siegner (b) (4)	07 Oct 2020 19:11:01

US3552191

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:36:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Joan Siegner (b) (4)	07 Oct 2020 19:11:01

US3552191

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'Mar 2020'	System	07 Oct 2020 19:11:01

US3552191

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '2020'	System	07 Oct 2020 19:11:01

US3552191

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 19:11:01

US3552191

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 19:11:01

US3552191

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:36:39

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 23:20:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 23:20:34
Data point term sent to Coder	System	08 Oct 2020 15:53:05
User entered 'seasonal allergies'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:53:00

US3552191

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:53:00

US3552191

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '1'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:53:00

US3552191

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:36:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:53:00

US3552191

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:53:00

US3552191

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:36:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:53:00

US3552191

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 15:53:00

US3552191

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 15:53:00

US3552191

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 15:53:00

US3552191

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 15:53:00

US3552191

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:36:39

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 18:52:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	12 Oct 2020 18:52:26
Data point term sent to Coder	System	12 Oct 2020 18:51:51
User entered 'obstructive sleep apnea'	Joan Siegner (b) (4)	12 Oct 2020 18:51:41

US3552191

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered empty.	Joan Siegner (b) (4)	12 Oct 2020 18:51:41

US3552191

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '1'	Joan Siegner (b) (4)	12 Oct 2020 18:51:41

US3552191

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:36:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'Yes (Y)'	Joan Siegner (b) (4)	12 Oct 2020 18:51:41

US3552191

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered empty.	Joan Siegner (b) (4)	12 Oct 2020 18:51:41

US3552191

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:36:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Joan Siegner (b) (4)	12 Oct 2020 18:51:41

US3552191

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 18:51:41

US3552191

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 18:51:41

US3552191

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 18:51:41

US3552191

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 18:51:41

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:01:32

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:01:32

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '13:00'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:01:32

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '26 Aug 2020 13:00'	System	27 Aug 2020 15:01:32

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '65' in	Stanley Dublin (b) (4)	27 Aug 2020 15:01:32
DataPoint set to visible.	(b) (4) System	26 Aug 2020 19:58:54

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '171.2' lb	Stanley Dublin (b) (4)	27 Aug 2020 15:01:32
DataPoint set to visible.	(b) (4) System	26 Aug 2020 19:58:54

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '28.54874'	System	17 Sep 2020 00:04:23
User entered '28.5'	System	27 Aug 2020 15:01:32
DataPoint set to visible.	System	26 Aug 2020 19:58:54

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	27 Aug 2020 15:01:32
DataPoint set to visible.	System	26 Aug 2020 19:58:54

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:01:32

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:01:32

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:01:32

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:01:32

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	27 Aug 2020 15:01:32

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:01:32

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	27 Aug 2020 15:01:32

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:01:32

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Aug 2020 15:01:32

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:01:32

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Aug 2020 15:01:32

US3552191

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:01:41

US3552191

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:01:41

US3552191

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:36:39

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:02:15

US3552191

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:36:39

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:02:15

US3552191

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:36:39

[If No, what is the reason?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 11:36:07
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'done' (Site from DM).	Joan Siegner (b) (4)	03 Oct 2020 16:09:06
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 09:31:45
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Stanley Doublin (b) (4)	27 Aug 2020 15:02:15

US3552191

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:36:39

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:02:15

US3552191

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:36:39

[If Surgically sterile, date of surgery \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:02:15

US3552191

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:36:39

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:02:15

US3552191

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'un UNK 2003'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:02:15

US3552191

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:36:39

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:02:15

US3552191

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

US3552191

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

US3552191

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

US3552191

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

US3552191

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

US3552191

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

US3552191

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

US3552191

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

US3552191

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

US3552191

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

US3552191

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

US3552191

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:39

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

US3552191

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:39

[Specify](#)

Audit	User	Time (GMT)
User entered 'babysits grandchildren (ages 9, 5, and two are 3 years old) 1 - 3 times a week, grocery shopping twice a week, attends church services weekly, wears mask when out.'	Stanley Dublin (b) (4)	27 Aug 2020 15:04:54

US3552191

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:39

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

US3552191

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

US3552191

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

US3552191

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

US3552191

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4)	27 Aug 2020 15:04:54
	(b) (4)	

US3552191

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '1'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

US3552191

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:39

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

US3552191

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:39

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

US3552191

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:36:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:04

US3552191

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:04

US3552191

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:04

US3552191

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:36:39

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	27 Aug 2020 15:05:04

US3552191

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '26 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	26 Aug 2020 19:59:24

US3552191

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '188537'	RWS_ENDPOINT ENDPOINT (b) (4) 	26 Aug 2020 19:59:24

US3552191

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) 	26 Aug 2020 19:59:24

US3552191

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:05:15

US3552191

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:15

US3552191

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:15

US3552191

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:36:39

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	14 Sep 2020 19:11:59
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:15

US3552191

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:36:39

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:15

US3552191

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4)	21 Sep 2020 17:31:02
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 08:08:01
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:08:00

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:36:39

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:36:39

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:36:39

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:36:39

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:39

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '13:00'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '26 Aug 2020 13:00'	System	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:39

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.6' F	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:39

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:39

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '90'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '12'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '118'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '74'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:36:39

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:36:39

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:39

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:06:32

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:06:32

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:06:32

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '15:50'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:06:32

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '26 Aug 2020 15:50'	System	27 Aug 2020 15:06:32

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:39

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.9' F	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:06:32

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:39

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:06:32

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:39

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:06:32

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '80'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:06:32

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	27 Aug 2020 15:06:32

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '16'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:06:32

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	27 Aug 2020 15:06:32

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '122'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:06:32

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Aug 2020 15:06:32

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '72'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:06:32

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Aug 2020 15:06:32

US3552191

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:06:38

US3552191

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:39

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:06:38

US3552191

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:36:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	26 Aug 2020 20:56:35
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	26 Aug 2020 20:56:35
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	26 Aug 2020 20:23:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 20:23:09

US3552191

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:36:39

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 20:23:09

US3552191

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 20:23:09

US3552191

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:36:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 20:23:09

US3552191

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '26 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 20:56:35
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 20:23:09

US3552191

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:36:39

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '15:20'	(b) (4), (b) (6)	26 Aug 2020 20:23:09

US3552191

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:36:39

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 15:20'	System	26 Aug 2020 20:56:35
User entered empty.	System	26 Aug 2020 20:23:09

US3552191

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:36:39

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	26 Aug 2020 20:23:09

US3552191

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:36:39

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	26 Aug 2020 20:23:09

US3552191

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:36:39

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 20:23:09

US3552191

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:06:54

US3552191

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:06:54

US3552191

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:39

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '14:38'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:06:54

US3552191

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 14:38'	System	27 Aug 2020 15:06:54

US3552191

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:36:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:07:09

US3552191

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:36:39

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Dublin (b) (4)	27 Aug 2020 15:07:09

US3552191

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:36:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:07:09

US3552191

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:36:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '14:45'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:07:09

US3552191

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:36:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 14:45'	System	27 Aug 2020 15:07:09

US3552191

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:36:39

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Dublin (b) (4)	27 Aug 2020 15:07:09

US3552191

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:36:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:07:09

US3552191

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:36:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:07:09

US3552191

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:36:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 15:07:09

US3552191

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:36:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joan Siegner (b) (4)	02 Sep 2020 16:53:01

US3552191

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:36:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 16:53:01

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-26T15:58:43', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '55257b81-0975-45fa-be2f-3d4299e2478f'	System	26 Aug 2020 20:59:06
User entered 'Yes (Y)'	System	26 Aug 2020 20:59:06

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-26T15:58:51', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '55257b81-0975-45fa-be2f-3d4299e2478f'	System	26 Aug 2020 20:59:06
User entered '97.1'	System	26 Aug 2020 20:59:06

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-26T15:58:56', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '55257b81-0975-45fa-be2f-3d4299e2478f'	System	26 Aug 2020 20:59:06
User entered 'No (N)'	System	26 Aug 2020 20:59:06

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-26T15:59:03', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '55257b81-0975-45fa-be2f-3d4299e2478f'	System	26 Aug 2020 20:59:06
User entered '26 Aug 2020 15:59'	System	26 Aug 2020 20:59:06

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 15:40'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 18:10'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T11:03:03', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '78444e04-316a-4bb5-8bbc-37986aa748dd'	System	27 Aug 2020 16:04:21
User entered 'Yes (Y)'	System	27 Aug 2020 16:04:21

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T11:03:59', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '78444e04-316a-4bb5-8bbc-37986aa748dd'	System	27 Aug 2020 16:04:21
User entered '97.5'	System	27 Aug 2020 16:04:21

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T11:04:05', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '78444e04-316a-4bb5-8bbc-37986aa748dd'	System	27 Aug 2020 16:04:21
User entered 'No (N)'	System	27 Aug 2020 16:04:21

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T11:04:14', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '78444e04-316a-4bb5-8bbc-37986aa748dd'	System	27 Aug 2020 16:04:21
User entered '27 Aug 2020 11:04'	System	27 Aug 2020 16:04:21

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 19:05'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 2'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T20:18:49', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '0f99fe23-59ce-4a87-9342-e96dd1c0aee6'	System	28 Aug 2020 01:19:07
User entered 'Yes (Y)'	System	28 Aug 2020 01:19:07

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T20:18:56', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '0f99fe23-59ce-4a87-9342-e96dd1c0aee6'	System	28 Aug 2020 01:19:07
User entered '99.5'	System	28 Aug 2020 01:19:07

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T20:19:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '0f99fe23-59ce-4a87-9342-e96dd1c0aee6'	System	28 Aug 2020 01:19:07
User entered 'No (N)'	System	28 Aug 2020 01:19:07

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T20:19:04', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '0f99fe23-59ce-4a87-9342-e96dd1c0aee6'	System	28 Aug 2020 01:19:07
User entered '27 Aug 2020 20:19'	System	28 Aug 2020 01:19:07

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:39

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 3'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-28T20:21:09', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '6f1016f5-9ed8-49af-abe2-2db41898181b'	System	29 Aug 2020 01:21:27
User entered 'Yes (Y)'	System	29 Aug 2020 01:21:27

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-28T20:21:15', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '6f1016f5-9ed8-49af-abe2-2db41898181b'	System	29 Aug 2020 01:21:27
User entered '99.9'	System	29 Aug 2020 01:21:27

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-28T20:21:20', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '6f1016f5-9ed8-49af-abe2-2db41898181b'	System	29 Aug 2020 01:21:27
User entered 'No (N)'	System	29 Aug 2020 01:21:27

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-28T20:21:25', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '6f1016f5-9ed8-49af-abe2-2db41898181b'	System	29 Aug 2020 01:21:27
User entered '28 Aug 2020 20:21'	System	29 Aug 2020 01:21:27

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 4'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-29T19:24:38', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'a3df19be-6801-400c-a729-34bc530a506c'	System	30 Aug 2020 00:24:51
User entered 'Yes (Y)'	System	30 Aug 2020 00:24:51

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-29T19:24:43', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'a3df19be-6801-400c-a729-34bc530a506c'	System	30 Aug 2020 00:24:51
User entered '99.0'	System	30 Aug 2020 00:24:51

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-29T19:24:45', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'a3df19be-6801-400c-a729-34bc530a506c'	System	30 Aug 2020 00:24:51
User entered 'No (N)'	System	30 Aug 2020 00:24:51

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-29T19:24:49', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'a3df19be-6801-400c-a729-34bc530a506c'	System	30 Aug 2020 00:24:51
User entered '29 Aug 2020 19:24'	System	30 Aug 2020 00:24:51

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 5'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-30T19:13:10', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '267f024b-84d4-41cb-a24b-53e61c589fba'	System	31 Aug 2020 00:13:25
User entered 'Yes (Y)'	System	31 Aug 2020 00:13:25

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-30T19:13:15', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '267f024b-84d4-41cb-a24b-53e61c589fba' User entered '98.7'	System	31 Aug 2020 00:13:25

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-30T19:13:18', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '267f024b-84d4-41cb-a24b-53e61c589fba'	System	31 Aug 2020 00:13:25
User entered 'No (N)'	System	31 Aug 2020 00:13:25

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-30T19:13:21', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '267f024b-84d4-41cb-a24b-53e61c589fba'	System	31 Aug 2020 00:13:25
User entered '30 Aug 2020 19:13'	System	31 Aug 2020 00:13:25

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 6'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-31T19:56:47', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1dad7ba1-2b6d-44fd-a068-624a07cc8266'	System	01 Sep 2020 00:57:01
User entered 'Yes (Y)'	System	01 Sep 2020 00:57:01

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:39

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-31T19:56:51', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1dad7ba1-2b6d-44fd-a068-624a07cc8266'	System	01 Sep 2020 00:57:01
User entered '98.4'	System	01 Sep 2020 00:57:01

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-31T19:56:54', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1dad7ba1-2b6d-44fd-a068-624a07cc8266'	System	01 Sep 2020 00:57:01
User entered 'No (N)'	System	01 Sep 2020 00:57:01

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-31T19:56:59', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1dad7ba1-2b6d-44fd-a068-624a07cc8266'	System	01 Sep 2020 00:57:01
User entered '31 Aug 2020 19:56'	System	01 Sep 2020 00:57:01

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 7'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-01T19:38:55', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'd109a038-47c7-4e22-88fb-b57f314d5587'	System	02 Sep 2020 00:39:10
User entered 'Yes (Y)'	System	02 Sep 2020 00:39:10

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:39

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-01T19:39:01', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'd109a038-47c7-4e22-88fb-b57f314d5587'	System	02 Sep 2020 00:39:10
User entered '98.9'	System	02 Sep 2020 00:39:10

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-01T19:39:04', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'd109a038-47c7-4e22-88fb-b57f314d5587'	System	02 Sep 2020 00:39:10
User entered 'No (N)'	System	02 Sep 2020 00:39:10

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-01T19:39:06', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'd109a038-47c7-4e22-88fb-b57f314d5587'	System	02 Sep 2020 00:39:10
User entered '01 Sep 2020 19:39'	System	02 Sep 2020 00:39:10

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-26T15:59:14', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '48f6a82e-c7c6-418b-902e-5dcfe38ca1cf'	System	26 Aug 2020 20:59:33
User entered 'None (1)'	System	26 Aug 2020 20:59:33

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-26T15:59:17', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '48f6a82e-c7c6-418b-902e-5dcfe38ca1cf'	System	26 Aug 2020 20:59:33
User entered 'No (N)'	System	26 Aug 2020 20:59:33

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-26T15:59:20', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '48f6a82e-c7c6-418b-902e-5dcfe38ca1cf'	System	26 Aug 2020 20:59:33
User entered 'No (N)'	System	26 Aug 2020 20:59:33

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-26T15:59:26', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '48f6a82e-c7c6-418b-902e-5dcfe38ca1cf'	System	26 Aug 2020 20:59:33
User entered 'None (1)'	System	26 Aug 2020 20:59:33

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-26T15:59:31', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '48f6a82e-c7c6-418b-902e-5dcfe38ca1cf'	System	26 Aug 2020 20:59:33
User entered '26 Aug 2020 15:59'	System	26 Aug 2020 20:59:33

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 15:40'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 18:10'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T11:04:25', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'f6b5851e-d94e-4a3a-9705-be23da5741f2'	System	27 Aug 2020 16:05:48
User entered 'None (1)'	System	27 Aug 2020 16:05:48

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T11:05:21', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'f6b5851e-d94e-4a3a-9705-be23da5741f2'	System	27 Aug 2020 16:05:48
User entered 'No (N)'	System	27 Aug 2020 16:05:48

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T11:05:25', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'f6b5851e-d94e-4a3a-9705-be23da5741f2'	System	27 Aug 2020 16:05:48
User entered 'No (N)'	System	27 Aug 2020 16:05:48

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T11:05:37', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'f6b5851e-d94e-4a3a-9705-be23da5741f2'	System	27 Aug 2020 16:05:48
User entered 'None (1)'	System	27 Aug 2020 16:05:48

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T11:05:46', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'f6b5851e-d94e-4a3a-9705-be23da5741f2'	System	27 Aug 2020 16:05:48
User entered '27 Aug 2020 11:05'	System	27 Aug 2020 16:05:48

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 19:05'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 2'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:39

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T20:19:15', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1afd9ced-d114-4d27-9e6c-b099e4eb9730'	System	28 Aug 2020 01:19:40
User entered 'Does not interfere with activity (2)'	System	28 Aug 2020 01:19:40

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T20:19:18', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1afd9ced-d114-4d27-9e6c-b099e4eb9730'	System	28 Aug 2020 01:19:40
User entered 'No (N)'	System	28 Aug 2020 01:19:40

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T20:19:21', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1afd9ced-d114-4d27-9e6c-b099e4eb9730'	System	28 Aug 2020 01:19:40
User entered 'No (N)'	System	28 Aug 2020 01:19:40

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T20:19:28', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1afd9ced-d114-4d27-9e6c-b099e4eb9730'	System	28 Aug 2020 01:19:40
User entered 'None (1)'	System	28 Aug 2020 01:19:40

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T20:19:38', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1afd9ced-d114-4d27-9e6c-b099e4eb9730'	System	28 Aug 2020 01:19:40
User entered '27 Aug 2020 20:19'	System	28 Aug 2020 01:19:40

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 3'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-28T20:21:30', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '9e5b801c-7d75-401b-83fd-e68d1162f823'	System	29 Aug 2020 01:21:51
User entered 'Does not interfere with activity (2)'	System	29 Aug 2020 01:21:51

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-28T20:21:32', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '9e5b801c-7d75-401b-83fd-e68d1162f823'	System	29 Aug 2020 01:21:51
User entered 'No (N)'	System	29 Aug 2020 01:21:51

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-28T20:21:36', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '9e5b801c-7d75-401b-83fd-e68d1162f823'	System	29 Aug 2020 01:21:51
User entered 'No (N)'	System	29 Aug 2020 01:21:51

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-28T20:21:40', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '9e5b801c-7d75-401b-83fd-e68d1162f823'	System	29 Aug 2020 01:21:51
User entered 'None (1)'	System	29 Aug 2020 01:21:51

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-28T20:21:47', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '9e5b801c-7d75-401b-83fd-e68d1162f823'	System	29 Aug 2020 01:21:51
User entered '28 Aug 2020 20:21'	System	29 Aug 2020 01:21:51

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 4'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-29T19:24:58', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '09df3756-a299-4f68-a816-074f7922dfa8'	System	30 Aug 2020 00:25:17
User entered 'Does not interfere with activity (2)'	System	30 Aug 2020 00:25:17

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-29T19:25:01', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '09df3756-a299-4f68-a816-074f7922dfa8'	System	30 Aug 2020 00:25:17
User entered 'No (N)'	System	30 Aug 2020 00:25:17

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-29T19:25:04', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '09df3756-a299-4f68-a816-074f7922dfa8'	System	30 Aug 2020 00:25:17
User entered 'No (N)'	System	30 Aug 2020 00:25:17

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-29T19:25:09', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '09df3756-a299-4f68-a816-074f7922dfa8'	System	30 Aug 2020 00:25:17
User entered 'None (1)'	System	30 Aug 2020 00:25:17

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-29T19:25:14', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '09df3756-a299-4f68-a816-074f7922dfa8'	System	30 Aug 2020 00:25:17
User entered '29 Aug 2020 19:25'	System	30 Aug 2020 00:25:17

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 5'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:39

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-30T19:13:25', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '16d26174-73d8-4456-b265-ba6d6e6fa100'	System	31 Aug 2020 00:15:38
User entered 'None (1)'	System	31 Aug 2020 00:15:38

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-30T19:13:28', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '16d26174-73d8-4456-b265-ba6d6e6fa100'	System	31 Aug 2020 00:15:38
User entered 'No (N)'	System	31 Aug 2020 00:15:38

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-30T19:13:31', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '16d26174-73d8-4456-b265-ba6d6e6fa100'	System	31 Aug 2020 00:15:38
User entered 'No (N)'	System	31 Aug 2020 00:15:38

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-30T19:13:34', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '16d26174-73d8-4456-b265-ba6d6e6fa100'	System	31 Aug 2020 00:15:38
User entered 'None (1)'	System	31 Aug 2020 00:15:38

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-30T19:13:38', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '16d26174-73d8-4456-b265-ba6d6e6fa100'	System	31 Aug 2020 00:15:38
User entered '30 Aug 2020 19:13'	System	31 Aug 2020 00:15:38

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 6'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-31T19:57:03', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c3868d94-c1ef-4360-a0d0-742094fffb07'	System	01 Sep 2020 00:57:22
User entered 'None (1)'	System	01 Sep 2020 00:57:22

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-31T19:57:06', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c3868d94-c1ef-4360-a0d0-742094fffb07'	System	01 Sep 2020 00:57:22
User entered 'No (N)'	System	01 Sep 2020 00:57:22

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-31T19:57:09', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c3868d94-c1ef-4360-a0d0-742094fffb07'	System	01 Sep 2020 00:57:22
User entered 'No (N)'	System	01 Sep 2020 00:57:22

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-31T19:57:12', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c3868d94-c1ef-4360-a0d0-742094fffb07'	System	01 Sep 2020 00:57:22
User entered 'None (1)'	System	01 Sep 2020 00:57:22

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-31T19:57:20', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c3868d94-c1ef-4360-a0d0-742094fffb07'	System	01 Sep 2020 00:57:22
User entered '31 Aug 2020 19:57'	System	01 Sep 2020 00:57:22

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 7'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:39

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-01T19:39:10', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '3a246c79-a7f5-4020-a0b7-c4234f32d238'	System	02 Sep 2020 00:39:29
User entered 'None (1)'	System	02 Sep 2020 00:39:29

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-01T19:39:15', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '3a246c79-a7f5-4020-a0b7-c4234f32d238'	System	02 Sep 2020 00:39:29
User entered 'No (N)'	System	02 Sep 2020 00:39:29

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-01T19:39:18', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '3a246c79-a7f5-4020-a0b7-c4234f32d238'	System	02 Sep 2020 00:39:29
User entered 'No (N)'	System	02 Sep 2020 00:39:29

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-01T19:39:21', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '3a246c79-a7f5-4020-a0b7-c4234f32d238'	System	02 Sep 2020 00:39:29
User entered 'None (1)'	System	02 Sep 2020 00:39:29

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-01T19:39:25', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '3a246c79-a7f5-4020-a0b7-c4234f32d238'	System	02 Sep 2020 00:39:29
User entered '01 Sep 2020 19:39'	System	02 Sep 2020 00:39:29

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-26T15:59:36', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '8163f7b9-1022-445a-8c39-f9ba074cd8c2'	System	26 Aug 2020 21:00:07
User entered 'None (0)'	System	26 Aug 2020 21:00:07

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-26T15:59:39', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '8163f7b9-1022-445a-8c39-f9ba074cd8c2'	System	26 Aug 2020 21:00:07
User entered 'None (0)'	System	26 Aug 2020 21:00:07

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-26T15:59:41', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '8163f7b9-1022-445a-8c39-f9ba074cd8c2'	System	26 Aug 2020 21:00:07
User entered 'None (0)'	System	26 Aug 2020 21:00:07

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-26T15:59:44', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '8163f7b9-1022-445a-8c39-f9ba074cd8c2'	System	26 Aug 2020 21:00:07
User entered 'None (0)'	System	26 Aug 2020 21:00:07

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-26T15:59:46', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '8163f7b9-1022-445a-8c39-f9ba074cd8c2'	System	26 Aug 2020 21:00:07
User entered 'None (0)'	System	26 Aug 2020 21:00:07

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-26T15:59:48', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '8163f7b9-1022-445a-8c39-f9ba074cd8c2'	System	26 Aug 2020 21:00:07
User entered 'None (0)'	System	26 Aug 2020 21:00:07

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-26T15:59:52', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '8163f7b9-1022-445a-8c39-f9ba074cd8c2'	System	26 Aug 2020 21:00:07
User entered 'No (N)'	System	26 Aug 2020 21:00:07

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-26T16:00:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '8163f7b9-1022-445a-8c39-f9ba074cd8c2'	System	26 Aug 2020 21:00:07
User entered '26 Aug 2020 16:00'	System	26 Aug 2020 21:00:07

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 15:40'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 18:10'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T11:05:51', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '47d7020b-930c-46e0-906a-3b3e73ce5001'	System	27 Aug 2020 16:06:19
User entered 'None (0)'	System	27 Aug 2020 16:06:19

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T11:05:54', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '47d7020b-930c-46e0-906a-3b3e73ce5001'	System	27 Aug 2020 16:06:19
User entered 'None (0)'	System	27 Aug 2020 16:06:19

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T11:05:57', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '47d7020b-930c-46e0-906a-3b3e73ce5001'	System	27 Aug 2020 16:06:19
User entered 'None (0)'	System	27 Aug 2020 16:06:19

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T11:06:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '47d7020b-930c-46e0-906a-3b3e73ce5001'	System	27 Aug 2020 16:06:19
User entered 'None (0)'	System	27 Aug 2020 16:06:19

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T11:06:02', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '47d7020b-930c-46e0-906a-3b3e73ce5001'	System	27 Aug 2020 16:06:19
User entered 'None (0)'	System	27 Aug 2020 16:06:19

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T11:06:05', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '47d7020b-930c-46e0-906a-3b3e73ce5001'	System	27 Aug 2020 16:06:19
User entered 'None (0)'	System	27 Aug 2020 16:06:19

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T11:06:08', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '47d7020b-930c-46e0-906a-3b3e73ce5001'	System	27 Aug 2020 16:06:19
User entered 'No (N)'	System	27 Aug 2020 16:06:19

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T11:06:17', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '47d7020b-930c-46e0-906a-3b3e73ce5001'	System	27 Aug 2020 16:06:19
User entered '27 Aug 2020 11:06'	System	27 Aug 2020 16:06:19

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 19:05'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 2'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:39

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T20:19:49', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '9dc9c4e3-7060-4952-ba37-bc67c276587e' User entered 'None (0)'	System	28 Aug 2020 01:20:24
	System	28 Aug 2020 01:20:24

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:39

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T20:19:56', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '9dc9c4e3-7060-4952-ba37-bc67c276587e'	System	28 Aug 2020 01:20:24
User entered 'Some interference with activity (2)'	System	28 Aug 2020 01:20:24

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T20:20:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '9dc9c4e3-7060-4952-ba37-bc67c276587e'	System	28 Aug 2020 01:20:24
User entered 'None (0)'	System	28 Aug 2020 01:20:24

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T20:20:04', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '9dc9c4e3-7060-4952-ba37-bc67c276587e' User entered 'None (0)'	System	28 Aug 2020 01:20:24
	System	28 Aug 2020 01:20:24

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T20:20:07', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '9dc9c4e3-7060-4952-ba37-bc67c276587e'	System	28 Aug 2020 01:20:24
User entered 'None (0)'	System	28 Aug 2020 01:20:24

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:39

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T20:20:09', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '9dc9c4e3-7060-4952-ba37-bc67c276587e' User entered 'None (0)'	System	28 Aug 2020 01:20:24
	System	28 Aug 2020 01:20:24

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T20:20:12', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '9dc9c4e3-7060-4952-ba37-bc67c276587e'	System	28 Aug 2020 01:20:24
User entered 'No (N)'	System	28 Aug 2020 01:20:24

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:39

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T20:20:22', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '9dc9c4e3-7060-4952-ba37-bc67c276587e'	System	28 Aug 2020 01:20:24
User entered '27 Aug 2020 20:20'	System	28 Aug 2020 01:20:24

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:39

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 3'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:39

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-28T20:21:53', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '930dd489-6df5-46e6-acad-a2661424def8'	System	29 Aug 2020 01:22:24
User entered 'None (0)'	System	29 Aug 2020 01:22:24

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:39

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-28T20:21:58', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '930dd489-6df5-46e6-acad-a2661424def8'	System	29 Aug 2020 01:22:24
User entered 'No interference with activity (1)'	System	29 Aug 2020 01:22:24

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-28T20:22:01', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '930dd489-6df5-46e6-acad-a2661424def8'	System	29 Aug 2020 01:22:24
User entered 'None (0)'	System	29 Aug 2020 01:22:24

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-28T20:22:04', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '930dd489-6df5-46e6-acad-a2661424def8'	System	29 Aug 2020 01:22:24
User entered 'None (0)'	System	29 Aug 2020 01:22:24

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-28T20:22:06', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '930dd489-6df5-46e6-acad-a2661424def8'	System	29 Aug 2020 01:22:24
User entered 'None (0)'	System	29 Aug 2020 01:22:24

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:39

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-28T20:22:08', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '930dd489-6df5-46e6-acad-a2661424def8'	System	29 Aug 2020 01:22:24
User entered 'None (0)'	System	29 Aug 2020 01:22:24

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-28T20:22:11', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '930dd489-6df5-46e6-acad-a2661424def8'	System	29 Aug 2020 01:22:24
User entered 'No (N)'	System	29 Aug 2020 01:22:24

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:39

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-28T20:22:21', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '930dd489-6df5-46e6-acad-a2661424def8'	System	29 Aug 2020 01:22:24
User entered '28 Aug 2020 20:22'	System	29 Aug 2020 01:22:24

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 4'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:39

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-29T19:25:21', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '101211df-0847-46ff-9c15-7d5fdbd8632c'	System	30 Aug 2020 00:25:47
User entered 'None (0)'	System	30 Aug 2020 00:25:47

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:39

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-29T19:25:25', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '101211df-0847-46ff-9c15-7d5fdbd8632c'	System	30 Aug 2020 00:25:47
User entered 'No interference with activity (1)'	System	30 Aug 2020 00:25:47

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-29T19:25:28', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '101211df-0847-46ff-9c15-7d5fdbd8632c'	System	30 Aug 2020 00:25:47
User entered 'None (0)'	System	30 Aug 2020 00:25:47

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-29T19:25:30', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '101211df-0847-46ff-9c15-7d5fdbd8632c'	System	30 Aug 2020 00:25:47
User entered 'None (0)'	System	30 Aug 2020 00:25:47

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-29T19:25:32', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '101211df-0847-46ff-9c15-7d5fdbd8632c'	System	30 Aug 2020 00:25:47
User entered 'None (0)'	System	30 Aug 2020 00:25:47

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:39

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-29T19:25:35', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '101211df-0847-46ff-9c15-7d5fdbd8632c'	System	30 Aug 2020 00:25:47
User entered 'None (0)'	System	30 Aug 2020 00:25:47

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-29T19:25:38', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '101211df-0847-46ff-9c15-7d5fdbd8632c'	System	30 Aug 2020 00:25:47
User entered 'No (N)'	System	30 Aug 2020 00:25:47

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:39

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-29T19:25:43', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '101211df-0847-46ff-9c15-7d5fdbd8632c'	System	30 Aug 2020 00:25:47
User entered '29 Aug 2020 19:25'	System	30 Aug 2020 00:25:47

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 5'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:39

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-30T19:13:44', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '262cf109-2835-48d0-ab6b-d37cb42a5f1b'	System	31 Aug 2020 00:15:50
User entered 'None (0)'	System	31 Aug 2020 00:15:50

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:39

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-30T19:13:47', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '262cf109-2835-48d0-ab6b-d37cb42a5f1b'	System	31 Aug 2020 00:15:50
User entered 'None (0)'	System	31 Aug 2020 00:15:50

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-30T19:13:49', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '262cf109-2835-48d0-ab6b-d37cb42a5f1b'	System	31 Aug 2020 00:15:50
User entered 'None (0)'	System	31 Aug 2020 00:15:50

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-30T19:13:51', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '262cf109-2835-48d0-ab6b-d37cb42a5f1b'	System	31 Aug 2020 00:15:50
User entered 'None (0)'	System	31 Aug 2020 00:15:50

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-30T19:13:53', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '262cf109-2835-48d0-ab6b-d37cb42a5f1b'	System	31 Aug 2020 00:15:50
User entered 'None (0)'	System	31 Aug 2020 00:15:50

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:39

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-30T19:13:55', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '262cf109-2835-48d0-ab6b-d37cb42a5f1b'	System	31 Aug 2020 00:15:50
User entered 'None (0)'	System	31 Aug 2020 00:15:50

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-30T19:13:59', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '262cf109-2835-48d0-ab6b-d37cb42a5f1b'	System	31 Aug 2020 00:15:50
User entered 'No (N)'	System	31 Aug 2020 00:15:50

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:39

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-30T19:14:05', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '262cf109-2835-48d0-ab6b-d37cb42a5f1b'	System	31 Aug 2020 00:15:50
User entered '30 Aug 2020 19:14'	System	31 Aug 2020 00:15:50

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 6'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:39

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-31T19:57:25', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '935a00d0-9f85-46f2-a9fc-bd8469af02e0'	System	01 Sep 2020 00:57:50
User entered 'None (0)'	System	01 Sep 2020 00:57:50

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:39

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-31T19:57:28', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '935a00d0-9f85-46f2-a9fc-bd8469af02e0'	System	01 Sep 2020 00:57:50
User entered 'None (0)'	System	01 Sep 2020 00:57:50

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-31T19:57:31', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '935a00d0-9f85-46f2-a9fc-bd8469af02e0'	System	01 Sep 2020 00:57:50
User entered 'None (0)'	System	01 Sep 2020 00:57:50

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-31T19:57:33', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '935a00d0-9f85-46f2-a9fc-bd8469af02e0'	System	01 Sep 2020 00:57:50
User entered 'None (0)'	System	01 Sep 2020 00:57:50

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-31T19:57:35', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '935a00d0-9f85-46f2-a9fc-bd8469af02e0'	System	01 Sep 2020 00:57:50
User entered 'None (0)'	System	01 Sep 2020 00:57:50

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:39

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-31T19:57:38', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '935a00d0-9f85-46f2-a9fc-bd8469af02e0'	System	01 Sep 2020 00:57:50
User entered 'None (0)'	System	01 Sep 2020 00:57:50

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-31T19:57:41', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '935a00d0-9f85-46f2-a9fc-bd8469af02e0'	System	01 Sep 2020 00:57:50
User entered 'No (N)'	System	01 Sep 2020 00:57:50

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:39

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-31T19:57:49', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '935a00d0-9f85-46f2-a9fc-bd8469af02e0' User entered '31 Aug 2020 19:57'	System	01 Sep 2020 00:57:50
	System	01 Sep 2020 00:57:50

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 7'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:39

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-01T19:39:28', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'ca2dbb0c-b636-49f7-b448-e8ea6548a81a'	System	02 Sep 2020 00:39:51
User entered 'None (0)'	System	02 Sep 2020 00:39:51

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:39

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-01T19:39:30', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'ca2dbb0c-b636-49f7-b448-e8ea6548a81a'	System	02 Sep 2020 00:39:51
User entered 'None (0)'	System	02 Sep 2020 00:39:51

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-01T19:39:33', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'ca2dbb0c-b636-49f7-b448-e8ea6548a81a'	System	02 Sep 2020 00:39:51
User entered 'None (0)'	System	02 Sep 2020 00:39:51

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-01T19:39:34', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'ca2dbb0c-b636-49f7-b448-e8ea6548a81a' User entered 'None (0)'	System	02 Sep 2020 00:39:51
	System	02 Sep 2020 00:39:51

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-01T19:39:36', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'ca2dbb0c-b636-49f7-b448-e8ea6548a81a'	System	02 Sep 2020 00:39:51
User entered 'None (0)'	System	02 Sep 2020 00:39:51

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:39

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-01T19:39:38', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'ca2dbb0c-b636-49f7-b448-e8ea6548a81a'	System	02 Sep 2020 00:39:51
User entered 'None (0)'	System	02 Sep 2020 00:39:51

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-01T19:39:42', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'ca2dbb0c-b636-49f7-b448-e8ea6548a81a'	System	02 Sep 2020 00:39:51
User entered 'No (N)'	System	02 Sep 2020 00:39:51

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:39

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-01T19:39:48', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'ca2dbb0c-b636-49f7-b448-e8ea6548a81a'	System	02 Sep 2020 00:39:51
User entered '01 Sep 2020 19:39'	System	02 Sep 2020 00:39:51

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joan Siegner (b) (4)	02 Sep 2020 16:53:21

US3552191

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:21:43
User entered '2 Sep 2020'	Joan Siegner (b) (4)	02 Sep 2020 16:53:21

US3552191

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Joan Siegner (b) (4)	02 Sep 2020 16:53:21

US3552191

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Joan Siegner (b) (4)	02 Sep 2020 16:53:21

US3552191

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	09 Sep 2020 19:57:02

US3552191

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 19:57:02

US3552191

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	09 Sep 2020 19:57:10

US3552191

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:21:29
User entered '9 Sep 2020'	Heather Douds (b) (4)	09 Sep 2020 19:57:10

US3552191

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Heather Douds (b) (4) (b) (4)	09 Sep 2020 19:57:10

US3552191

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Heather Douds (b) (4) (b) (4)	09 Sep 2020 19:57:10

US3552191

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	16 Sep 2020 17:20:05

US3552191

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 17:20:05

US3552191

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	16 Sep 2020 17:20:26

US3552191

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	16 Sep 2020 17:20:26

US3552191

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	16 Sep 2020 17:20:26

US3552191

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	16 Sep 2020 17:20:26

US3552191

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	23 Sep 2020 14:22:24
	(b) (4)	

US3552191

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 14:22:24

US3552191

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:36:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:14:57

US3552191

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:14:57

US3552191

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:14:57

US3552191

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:36:39

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	23 Sep 2020 17:14:57

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:39

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:15:22

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:15:22

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:15:22

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '08:55'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:15:22

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '23 Sep 2020 08:55'	System	23 Sep 2020 17:15:22

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:39

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.3' F	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 17:15:22

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:39

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:15:22

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:39

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:15:22

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '97'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:15:22

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	23 Sep 2020 17:15:22

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '14'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:15:22

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	23 Sep 2020 17:15:22

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '119'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:15:22

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Sep 2020 17:15:22

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '71'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:15:22

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Sep 2020 17:15:22

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:39

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:17:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:17:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:17:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '10:04'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:17:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '23 Sep 2020 10:04'	System	23 Sep 2020 17:17:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:39

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.4' F	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:17:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:39

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:17:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:39

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:17:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '90'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:17:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	23 Sep 2020 17:17:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '14'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:17:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	23 Sep 2020 17:17:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '119'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:17:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Sep 2020 17:17:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '72'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:17:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Sep 2020 17:17:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:20:53

US3552191

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:39

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:20:53

US3552191

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:36:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	23 Sep 2020 14:40:04
	(b) (4)	

US3552191

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:36:39

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Cassandra Zehenny (b) (4)	23 Sep 2020 14:40:04
	(b) (4)	

US3552191

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	Cassandra Zehenny (b) (4)	23 Sep 2020 14:40:04
	(b) (4)	

US3552191

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:36:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	23 Sep 2020 14:40:04

US3552191

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:36:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Cassandra Zehenny (b) (4)	23 Sep 2020 14:40:04
	(b) (4)	

US3552191

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:36:39

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '09:34'	Cassandra Zehenny (b) (4)	23 Sep 2020 14:40:04
	(b) (4)	

US3552191

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:36:39

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 09:34'	System	23 Sep 2020 14:40:04

US3552191

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:36:39

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Cassandra Zehenny (b) (4)	23 Sep 2020 14:40:04
	(b) (4)	

US3552191

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:36:39

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	23 Sep 2020 14:40:04

US3552191

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:36:39

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	23 Sep 2020 14:40:04

US3552191

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:21:05

US3552191

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:21:05

US3552191

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:39

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '09:12'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:21:05

US3552191

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 09:12'	System	23 Sep 2020 17:21:05

US3552191

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:36:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:21:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:36:39

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Dublin (b) (4)	23 Sep 2020 17:21:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:36:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:21:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:36:39

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '09:15'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:21:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:36:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 09:15'	System	23 Sep 2020 17:21:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:36:39

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Dublin (b) (4)	23 Sep 2020 17:21:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:36:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:21:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:36:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:21:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:36:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 17:21:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	30 Sep 2020 17:04:09

US3552191

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 17:04:09

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T10:02:50', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'cfa8b757-8ee9-4a8c-95c8-9d9ba6c0a6ea'	System	23 Sep 2020 15:03:21
User entered 'Yes (Y)'	System	23 Sep 2020 15:03:21

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T10:02:57', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'cfa8b757-8ee9-4a8c-95c8-9d9ba6c0a6ea'	System	23 Sep 2020 15:03:21
User entered '98.4'	System	23 Sep 2020 15:03:21

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T10:03:01', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'cfa8b757-8ee9-4a8c-95c8-9d9ba6c0a6ea'	System	23 Sep 2020 15:03:21
User entered 'No (N)'	System	23 Sep 2020 15:03:21

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T10:03:07', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'cfa8b757-8ee9-4a8c-95c8-9d9ba6c0a6ea' User entered '23 Sep 2020 10:03'	System	23 Sep 2020 15:03:21
	System	23 Sep 2020 15:03:21

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 09:54'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:24'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T18:25:10', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'a3205a4c-2afb-4491-96d7-dae5258c183e' User entered 'Yes (Y)'	System	23 Sep 2020 23:25:26
	System	23 Sep 2020 23:25:26

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T18:25:16', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'a3205a4c-2afb-4491-96d7-dae5258c183e' User entered '97.3'	System	23 Sep 2020 23:25:26
	System	23 Sep 2020 23:25:26

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T18:25:20', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'a3205a4c-2afb-4491-96d7-dae5258c183e'	System	23 Sep 2020 23:25:26
User entered 'No (N)'	System	23 Sep 2020 23:25:26

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T18:25:23', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'a3205a4c-2afb-4491-96d7-dae5258c183e' User entered '23 Sep 2020 18:25'	System	23 Sep 2020 23:25:26
	System	23 Sep 2020 23:25:26

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 13:19'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 2'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-24T18:39:43', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '847734cf-81b8-4127-9627-94066ba4e1cd'	System	24 Sep 2020 23:40:02
User entered 'Yes (Y)'	System	24 Sep 2020 23:40:02

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-24T18:39:50', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '847734cf-81b8-4127-9627-94066ba4e1cd'	System	24 Sep 2020 23:40:02
User entered '101.2'	System	24 Sep 2020 23:40:02

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-24T18:39:53', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '847734cf-81b8-4127-9627-94066ba4e1cd'	System	24 Sep 2020 23:40:02
User entered 'No (N)'	System	24 Sep 2020 23:40:02

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-24T18:39:58', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '847734cf-81b8-4127-9627-94066ba4e1cd'	System	24 Sep 2020 23:40:02
User entered '24 Sep 2020 18:39'	System	24 Sep 2020 23:40:02

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 3'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-25T18:57:58', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'ce2045ca-96f9-4d35-a279-dfc64b95208f'	System	25 Sep 2020 23:58:24
User entered 'Yes (Y)'	System	25 Sep 2020 23:58:24

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:39

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-25T18:58:03', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'ce2045ca-96f9-4d35-a279-dfc64b95208f'	System	25 Sep 2020 23:58:24
User entered '98.8'	System	25 Sep 2020 23:58:24

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-25T18:58:13', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'ce2045ca-96f9-4d35-a279-dfc64b95208f'	System	25 Sep 2020 23:58:24
User entered 'No (N)'	System	25 Sep 2020 23:58:24

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-25T18:58:18', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'ce2045ca-96f9-4d35-a279-dfc64b95208f' User entered '25 Sep 2020 18:58'	System	25 Sep 2020 23:58:24
	System	25 Sep 2020 23:58:24

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 4'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-26T19:43:10', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '3a8ac345-dca9-435d-b09b-44a1429ad9f8'	System	27 Sep 2020 00:43:25
User entered 'Yes (Y)'	System	27 Sep 2020 00:43:25

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-26T19:43:15', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '3a8ac345-dca9-435d-b09b-44a1429ad9f8'	System	27 Sep 2020 00:43:25
User entered '98.7'	System	27 Sep 2020 00:43:25

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-26T19:43:19', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '3a8ac345-dca9-435d-b09b-44a1429ad9f8'	System	27 Sep 2020 00:43:25
User entered 'No (N)'	System	27 Sep 2020 00:43:25

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-26T19:43:23', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '3a8ac345-dca9-435d-b09b-44a1429ad9f8'	System	27 Sep 2020 00:43:25
User entered '26 Sep 2020 19:43'	System	27 Sep 2020 00:43:25

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 5'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-27T18:45:12', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '5d039890-2daa-49a7-a6b0-eb98b01704c9'	System	27 Sep 2020 23:45:34
User entered 'Yes (Y)'	System	27 Sep 2020 23:45:34

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-27T18:45:24', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '5d039890-2daa-49a7-a6b0-eb98b01704c9'	System	27 Sep 2020 23:45:34
User entered '98.1'	System	27 Sep 2020 23:45:34

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-27T18:45:28', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '5d039890-2daa-49a7-a6b0-eb98b01704c9'	System	27 Sep 2020 23:45:34
User entered 'No (N)'	System	27 Sep 2020 23:45:34

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-27T18:45:32', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '5d039890-2daa-49a7-a6b0-eb98b01704c9'	System	27 Sep 2020 23:45:34
User entered '27 Sep 2020 18:45'	System	27 Sep 2020 23:45:34

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 6'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-28T20:14:08', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c8a88475-f1b5-4cf8-ae21-f913e46cc507'	System	29 Sep 2020 01:14:23
User entered 'Yes (Y)'	System	29 Sep 2020 01:14:23

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-28T20:14:13', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c8a88475-f1b5-4cf8-ae21-f913e46cc507'	System	29 Sep 2020 01:14:23
User entered '99.0'	System	29 Sep 2020 01:14:23

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-28T20:14:16', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c8a88475-f1b5-4cf8-ae21-f913e46cc507'	System	29 Sep 2020 01:14:23
User entered 'No (N)'	System	29 Sep 2020 01:14:23

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-28T20:14:20', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c8a88475-f1b5-4cf8-ae21-f913e46cc507'	System	29 Sep 2020 01:14:23
User entered '28 Sep 2020 20:14'	System	29 Sep 2020 01:14:23

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 7'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-29T22:11:14', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'f0fbed57-5643-473c-b49d-5d4b59f43b16'	System	30 Sep 2020 03:11:28
User entered 'Yes (Y)'	System	30 Sep 2020 03:11:28

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-29T22:11:20', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'f0fbed57-5643-473c-b49d-5d4b59f43b16'	System	30 Sep 2020 03:11:28
User entered '98.7'	System	30 Sep 2020 03:11:28

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-29T22:11:23', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'f0fbed57-5643-473c-b49d-5d4b59f43b16'	System	30 Sep 2020 03:11:28
User entered 'No (N)'	System	30 Sep 2020 03:11:28

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-29T22:11:26', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'f0fbed57-5643-473c-b49d-5d4b59f43b16'	System	30 Sep 2020 03:11:28
User entered '29 Sep 2020 22:11'	System	30 Sep 2020 03:11:28

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T10:03:13', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'cc5f2165-e4f1-40c3-a9ef-e2d45f50378e'	System	23 Sep 2020 15:03:44
User entered 'None (1)'	System	23 Sep 2020 15:03:44

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T10:03:25', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'cc5f2165-e4f1-40c3-a9ef-e2d45f50378e'	System	23 Sep 2020 15:03:44
User entered 'No (N)'	System	23 Sep 2020 15:03:44

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T10:03:29', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'cc5f2165-e4f1-40c3-a9ef-e2d45f50378e'	System	23 Sep 2020 15:03:44
User entered 'No (N)'	System	23 Sep 2020 15:03:44

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T10:03:33', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'cc5f2165-e4f1-40c3-a9ef-e2d45f50378e'	System	23 Sep 2020 15:03:44
User entered 'None (1)'	System	23 Sep 2020 15:03:44

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T10:03:40', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'cc5f2165-e4f1-40c3-a9ef-e2d45f50378e' User entered '23 Sep 2020 10:03'	System	23 Sep 2020 15:03:44
	System	23 Sep 2020 15:03:44

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 09:54'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:24'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T18:25:32', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'f1db838e-fa4d-4c65-9505-09716694d41f' User entered 'Does not interfere with activity (2)'	System	23 Sep 2020 23:25:48
	System	23 Sep 2020 23:25:48

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T18:25:35', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'f1db838e-fa4d-4c65-9505-09716694d41f'	System	23 Sep 2020 23:25:48
User entered 'No (N)'	System	23 Sep 2020 23:25:48

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T18:25:38', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'f1db838e-fa4d-4c65-9505-09716694d41f'	System	23 Sep 2020 23:25:48
User entered 'No (N)'	System	23 Sep 2020 23:25:48

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T18:25:43', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'f1db838e-fa4d-4c65-9505-09716694d41f'	System	23 Sep 2020 23:25:48
User entered 'None (1)'	System	23 Sep 2020 23:25:48

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T18:25:47', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'f1db838e-fa4d-4c65-9505-09716694d41f' User entered '23 Sep 2020 18:25'	System	23 Sep 2020 23:25:48
	System	23 Sep 2020 23:25:48

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 13:19'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 2'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:39

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-24T18:40:10', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '2c99dfa8-8f14-4377-9c60-ded3f9e0f8f3'	System	24 Sep 2020 23:41:08
User entered 'Does not interfere with activity (2)'	System	24 Sep 2020 23:41:08

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-24T18:40:31', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '2c99dfa8-8f14-4377-9c60-ded3f9e0f8f3'	System	24 Sep 2020 23:41:08
User entered 'No (N)'	System	24 Sep 2020 23:41:08

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-24T18:40:34', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '2c99dfa8-8f14-4377-9c60-ded3f9e0f8f3'	System	24 Sep 2020 23:41:08
User entered 'No (N)'	System	24 Sep 2020 23:41:08

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-24T18:40:39', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '2c99dfa8-8f14-4377-9c60-ded3f9e0f8f3'	System	24 Sep 2020 23:41:08
User entered 'None (1)'	System	24 Sep 2020 23:41:08

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-24T18:41:06', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '2c99dfa8-8f14-4377-9c60-ded3f9e0f8f3'	System	24 Sep 2020 23:41:08
User entered '24 Sep 2020 18:41'	System	24 Sep 2020 23:41:08

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 3'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-25T18:58:25', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '4242ef3d-c71d-44a4-89ce-e295a64f75d0'	System	25 Sep 2020 23:58:55
User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 23:58:55

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-25T18:58:28', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '4242ef3d-c71d-44a4-89ce-e295a64f75d0'	System	25 Sep 2020 23:58:55
User entered 'No (N)'	System	25 Sep 2020 23:58:55

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-25T18:58:30', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '4242ef3d-c71d-44a4-89ce-e295a64f75d0'	System	25 Sep 2020 23:58:55
User entered 'No (N)'	System	25 Sep 2020 23:58:55

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-25T18:58:46', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '4242ef3d-c71d-44a4-89ce-e295a64f75d0'	System	25 Sep 2020 23:58:55
User entered 'None (1)'	System	25 Sep 2020 23:58:55

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-25T18:58:51', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '4242ef3d-c71d-44a4-89ce-e295a64f75d0'	System	25 Sep 2020 23:58:55
User entered '25 Sep 2020 18:58'	System	25 Sep 2020 23:58:55

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 4'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-26T19:43:28', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1f13cce3-1723-4eb5-adca-08ceada098f9'	System	27 Sep 2020 00:44:05
User entered 'Does not interfere with activity (2)'	System	27 Sep 2020 00:44:05

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-26T19:43:31', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1f13cce3-1723-4eb5-adca-08ceada098f9'	System	27 Sep 2020 00:44:05
User entered 'No (N)'	System	27 Sep 2020 00:44:05

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-26T19:43:34', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1f13cce3-1723-4eb5-adca-08ceada098f9'	System	27 Sep 2020 00:44:05
User entered 'No (N)'	System	27 Sep 2020 00:44:05

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-26T19:43:53', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1f13cce3-1723-4eb5-adca-08ceada098f9'	System	27 Sep 2020 00:44:05
User entered 'None (1)'	System	27 Sep 2020 00:44:05

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-26T19:44:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1f13cce3-1723-4eb5-adca-08ceada098f9'	System	27 Sep 2020 00:44:05
User entered '26 Sep 2020 19:44'	System	27 Sep 2020 00:44:05

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 5'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:39

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-27T18:45:40', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '26861370-fddb-4d77-8575-c963bf71fb49'	System	27 Sep 2020 23:46:06
User entered 'Does not interfere with activity (2)'	System	27 Sep 2020 23:46:06

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-27T18:45:43', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '26861370-fddb-4d77-8575-c963bf71fb49'	System	27 Sep 2020 23:46:06
User entered 'No (N)'	System	27 Sep 2020 23:46:06

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-27T18:45:46', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '26861370-fddb-4d77-8575-c963bf71fb49'	System	27 Sep 2020 23:46:06
User entered 'No (N)'	System	27 Sep 2020 23:46:06

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-27T18:45:58', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '26861370-fddb-4d77-8575-c963bf71fb49'	System	27 Sep 2020 23:46:06
User entered 'None (1)'	System	27 Sep 2020 23:46:06

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-27T18:46:03', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '26861370-fddb-4d77-8575-c963bf71fb49'	System	27 Sep 2020 23:46:06
User entered '27 Sep 2020 18:46'	System	27 Sep 2020 23:46:06

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 6'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-28T20:14:31', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '59fc4a44-a941-438b-850b-fc0e5fd5b239'	System	29 Sep 2020 01:14:53
User entered 'Does not interfere with activity (2)'	System	29 Sep 2020 01:14:53

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-28T20:14:34', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '59fc4a44-a941-438b-850b-fc0e5fd5b239'	System	29 Sep 2020 01:14:53
User entered 'No (N)'	System	29 Sep 2020 01:14:53

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-28T20:14:36', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '59fc4a44-a941-438b-850b-fc0e5fd5b239'	System	29 Sep 2020 01:14:53
User entered 'No (N)'	System	29 Sep 2020 01:14:53

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-28T20:14:48', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '59fc4a44-a941-438b-850b-fc0e5fd5b239'	System	29 Sep 2020 01:14:53
User entered 'None (1)'	System	29 Sep 2020 01:14:53

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-28T20:14:50', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '59fc4a44-a941-438b-850b-fc0e5fd5b239'	System	29 Sep 2020 01:14:53
User entered '28 Sep 2020 20:14'	System	29 Sep 2020 01:14:53

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 7'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-29T22:11:41', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '6093be30-4c21-4bc8-83d8-9ab3c1678075'	System	30 Sep 2020 03:12:06
User entered 'None (1)'	System	30 Sep 2020 03:12:06

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-29T22:11:39', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '6093be30-4c21-4bc8-83d8-9ab3c1678075'	System	30 Sep 2020 03:12:06
User entered 'No (N)'	System	30 Sep 2020 03:12:06

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-29T22:11:44', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '6093be30-4c21-4bc8-83d8-9ab3c1678075'	System	30 Sep 2020 03:12:06
User entered 'No (N)'	System	30 Sep 2020 03:12:06

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-29T22:11:47', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '6093be30-4c21-4bc8-83d8-9ab3c1678075'	System	30 Sep 2020 03:12:06
User entered 'None (1)'	System	30 Sep 2020 03:12:06

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-29T22:12:01', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '6093be30-4c21-4bc8-83d8-9ab3c1678075'	System	30 Sep 2020 03:12:06
User entered '29 Sep 2020 22:12'	System	30 Sep 2020 03:12:06

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T10:03:45', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'daa05262-3604-449c-8385-e0d61f8b4073'	System	23 Sep 2020 15:04:11
User entered 'None (0)'	System	23 Sep 2020 15:04:11

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T10:03:47', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'daa05262-3604-449c-8385-e0d61f8b4073'	System	23 Sep 2020 15:04:11
User entered 'None (0)'	System	23 Sep 2020 15:04:11

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T10:03:49', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'daa05262-3604-449c-8385-e0d61f8b4073'	System	23 Sep 2020 15:04:11
User entered 'None (0)'	System	23 Sep 2020 15:04:11

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T10:03:54', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'daa05262-3604-449c-8385-e0d61f8b4073'	System	23 Sep 2020 15:04:11
User entered 'None (0)'	System	23 Sep 2020 15:04:11

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T10:03:56', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'daa05262-3604-449c-8385-e0d61f8b4073'	System	23 Sep 2020 15:04:11
User entered 'None (0)'	System	23 Sep 2020 15:04:11

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T10:03:58', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'daa05262-3604-449c-8385-e0d61f8b4073'	System	23 Sep 2020 15:04:11
User entered 'None (0)'	System	23 Sep 2020 15:04:11

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T10:04:03', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'daa05262-3604-449c-8385-e0d61f8b4073'	System	23 Sep 2020 15:04:11
User entered 'No (N)'	System	23 Sep 2020 15:04:11

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T10:04:09', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'daa05262-3604-449c-8385-e0d61f8b4073'	System	23 Sep 2020 15:04:11
User entered '23 Sep 2020 10:04'	System	23 Sep 2020 15:04:11

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 09:54'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:24'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T18:25:52', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c355627b-788f-42e8-97de-fa6973b0e538'	System	23 Sep 2020 23:26:20
User entered 'None (0)'	System	23 Sep 2020 23:26:20

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T18:25:55', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c355627b-788f-42e8-97de-fa6973b0e538'	System	23 Sep 2020 23:26:20
User entered 'None (0)'	System	23 Sep 2020 23:26:20

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T18:25:58', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c355627b-788f-42e8-97de-fa6973b0e538'	System	23 Sep 2020 23:26:20
User entered 'None (0)'	System	23 Sep 2020 23:26:20

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T18:26:01', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c355627b-788f-42e8-97de-fa6973b0e538'	System	23 Sep 2020 23:26:20
User entered 'None (0)'	System	23 Sep 2020 23:26:20

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T18:26:05', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c355627b-788f-42e8-97de-fa6973b0e538'	System	23 Sep 2020 23:26:20
User entered 'None (0)'	System	23 Sep 2020 23:26:20

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T18:26:08', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c355627b-788f-42e8-97de-fa6973b0e538'	System	23 Sep 2020 23:26:20
User entered 'None (0)'	System	23 Sep 2020 23:26:20

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T18:26:11', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c355627b-788f-42e8-97de-fa6973b0e538'	System	23 Sep 2020 23:26:20
User entered 'No (N)'	System	23 Sep 2020 23:26:20

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T18:26:18', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c355627b-788f-42e8-97de-fa6973b0e538'	System	23 Sep 2020 23:26:20
User entered '23 Sep 2020 18:26'	System	23 Sep 2020 23:26:20

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 13:19'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 2'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:39

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-24T18:41:13', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'bfe6cd49-97f3-413c-9d8b-a3e95cc4910b'	System	24 Sep 2020 23:42:17
User entered 'No interference with activity (1)'	System	24 Sep 2020 23:42:17

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:39

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-24T18:41:21', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'bfe6cd49-97f3-413c-9d8b-a3e95cc4910b'	System	24 Sep 2020 23:42:17
User entered 'Some interference with activity (2)'	System	24 Sep 2020 23:42:17

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-24T18:41:26', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'bfe6cd49-97f3-413c-9d8b-a3e95cc4910b'	System	24 Sep 2020 23:42:17
User entered 'Some interference with activity (2)'	System	24 Sep 2020 23:42:17

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-24T18:41:37', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'bfe6cd49-97f3-413c-9d8b-a3e95cc4910b'	System	24 Sep 2020 23:42:17
User entered 'Some interference with activity (2)'	System	24 Sep 2020 23:42:17

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-24T18:41:45', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'bfe6cd49-97f3-413c-9d8b-a3e95cc4910b'	System	24 Sep 2020 23:42:17
User entered 'None (0)'	System	24 Sep 2020 23:42:17

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:39

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-24T18:41:55', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'bfe6cd49-97f3-413c-9d8b-a3e95cc4910b'	System	24 Sep 2020 23:42:17
User entered 'No interference with activity (1)'	System	24 Sep 2020 23:42:17

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-24T18:41:59', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'bfe6cd49-97f3-413c-9d8b-a3e95cc4910b'	System	24 Sep 2020 23:42:17
User entered 'No (N)'	System	24 Sep 2020 23:42:17

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:39

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-24T18:42:15', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'bfe6cd49-97f3-413c-9d8b-a3e95cc4910b'	System	24 Sep 2020 23:42:17
User entered '24 Sep 2020 18:42'	System	24 Sep 2020 23:42:17

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 3'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:39

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-25T18:58:57', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '95248dcf-b95e-41e3-9061-f7e740c55f07'	System	25 Sep 2020 23:59:33
User entered 'No interference with activity (1)'	System	25 Sep 2020 23:59:33

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:39

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-25T18:59:01', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '95248dcf-b95e-41e3-9061-f7e740c55f07'	System	25 Sep 2020 23:59:33
User entered 'Some interference with activity (2)'	System	25 Sep 2020 23:59:33

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-25T18:59:06', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '95248dcf-b95e-41e3-9061-f7e740c55f07'	System	25 Sep 2020 23:59:33
User entered 'No interference with activity (1)'	System	25 Sep 2020 23:59:33

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-25T18:59:11', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '95248dcf-b95e-41e3-9061-f7e740c55f07'	System	25 Sep 2020 23:59:33
User entered 'No interference with activity (1)'	System	25 Sep 2020 23:59:33

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-25T18:59:15', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '95248dcf-b95e-41e3-9061-f7e740c55f07'	System	25 Sep 2020 23:59:33
User entered 'None (0)'	System	25 Sep 2020 23:59:33

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:39

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-25T18:59:18', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '95248dcf-b95e-41e3-9061-f7e740c55f07'	System	25 Sep 2020 23:59:33
User entered 'No interference with activity (1)'	System	25 Sep 2020 23:59:33

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-25T18:59:21', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '95248dcf-b95e-41e3-9061-f7e740c55f07'	System	25 Sep 2020 23:59:33
User entered 'No (N)'	System	25 Sep 2020 23:59:33

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:39

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-25T18:59:30', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '95248dcf-b95e-41e3-9061-f7e740c55f07'	System	25 Sep 2020 23:59:33
User entered '25 Sep 2020 18:59'	System	25 Sep 2020 23:59:33

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 4'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:39

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-26T19:44:07', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '0f380255-a160-4f95-b2ec-7da821ad4eff'	System	27 Sep 2020 00:44:49
User entered 'No interference with activity (1)'	System	27 Sep 2020 00:44:49

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:39

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-26T19:44:14', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '0f380255-a160-4f95-b2ec-7da821ad4eff'	System	27 Sep 2020 00:44:49
User entered 'Some interference with activity (2)'	System	27 Sep 2020 00:44:49

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-26T19:44:19', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '0f380255-a160-4f95-b2ec-7da821ad4eff'	System	27 Sep 2020 00:44:49
User entered 'No interference with activity (1)'	System	27 Sep 2020 00:44:49

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-26T19:44:26', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '0f380255-a160-4f95-b2ec-7da821ad4eff'	System	27 Sep 2020 00:44:49
User entered 'No interference with activity (1)'	System	27 Sep 2020 00:44:49

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-26T19:44:29', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '0f380255-a160-4f95-b2ec-7da821ad4eff'	System	27 Sep 2020 00:44:49
User entered 'None (0)'	System	27 Sep 2020 00:44:49

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:39

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-26T19:44:32', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '0f380255-a160-4f95-b2ec-7da821ad4eff'	System	27 Sep 2020 00:44:49
User entered 'No interference with activity (1)'	System	27 Sep 2020 00:44:49

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-26T19:44:35', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '0f380255-a160-4f95-b2ec-7da821ad4eff'	System	27 Sep 2020 00:44:49
User entered 'No (N)'	System	27 Sep 2020 00:44:49

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:39

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-26T19:44:46', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '0f380255-a160-4f95-b2ec-7da821ad4eff' User entered '26 Sep 2020 19:44'	System	27 Sep 2020 00:44:49
	System	27 Sep 2020 00:44:49

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 5'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:39

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-27T18:46:08', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'aed399f8-d68e-439b-beb8-25ab738e9a42'	System	27 Sep 2020 23:46:42
User entered 'None (0)'	System	27 Sep 2020 23:46:42

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:39

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-27T18:46:13', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'aed399f8-d68e-439b-beb8-25ab738e9a42'	System	27 Sep 2020 23:46:42
User entered 'Some interference with activity (2)'	System	27 Sep 2020 23:46:42

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-27T18:46:21', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'aed399f8-d68e-439b-beb8-25ab738e9a42'	System	27 Sep 2020 23:46:42
User entered 'None (0)'	System	27 Sep 2020 23:46:42

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-27T18:46:24', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'aed399f8-d68e-439b-beb8-25ab738e9a42'	System	27 Sep 2020 23:46:42
User entered 'None (0)'	System	27 Sep 2020 23:46:42

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-27T18:46:27', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'aed399f8-d68e-439b-beb8-25ab738e9a42'	System	27 Sep 2020 23:46:42
User entered 'None (0)'	System	27 Sep 2020 23:46:42

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:39

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-27T18:46:29', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'aed399f8-d68e-439b-beb8-25ab738e9a42'	System	27 Sep 2020 23:46:42
User entered 'None (0)'	System	27 Sep 2020 23:46:42

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-27T18:46:32', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'aed399f8-d68e-439b-beb8-25ab738e9a42'	System	27 Sep 2020 23:46:42
User entered 'No (N)'	System	27 Sep 2020 23:46:42

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:39

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-27T18:46:41', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'aed399f8-d68e-439b-beb8-25ab738e9a42'	System	27 Sep 2020 23:46:42
User entered '27 Sep 2020 18:46'	System	27 Sep 2020 23:46:42

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:39

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 6'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:39

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-28T20:14:55', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '874ebbd9-09cf-4d69-84be-fb5d0e8f98ca'	System	29 Sep 2020 01:15:30
User entered 'None (0)'	System	29 Sep 2020 01:15:30

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:39

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-28T20:15:25', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '874ebbd9-09cf-4d69-84be-fb5d0e8f98ca'	System	29 Sep 2020 01:15:30
User entered 'Some interference with activity (2)'	System	29 Sep 2020 01:15:30

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-28T20:15:04', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '874ebbd9-09cf-4d69-84be-fb5d0e8f98ca'	System	29 Sep 2020 01:15:30
User entered 'None (0)'	System	29 Sep 2020 01:15:30

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-28T20:15:07', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '874ebbd9-09cf-4d69-84be-fb5d0e8f98ca'	System	29 Sep 2020 01:15:30
User entered 'None (0)'	System	29 Sep 2020 01:15:30

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-28T20:15:09', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '874ebbd9-09cf-4d69-84be-fb5d0e8f98ca'	System	29 Sep 2020 01:15:30
User entered 'None (0)'	System	29 Sep 2020 01:15:30

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:39

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-28T20:15:12', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '874ebbd9-09cf-4d69-84be-fb5d0e8f98ca'	System	29 Sep 2020 01:15:30
User entered 'None (0)'	System	29 Sep 2020 01:15:30

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-28T20:15:15', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '874ebbd9-09cf-4d69-84be-fb5d0e8f98ca'	System	29 Sep 2020 01:15:30
User entered 'No (N)'	System	29 Sep 2020 01:15:30

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:39

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-28T20:15:28', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '874ebbd9-09cf-4d69-84be-fb5d0e8f98ca'	System	29 Sep 2020 01:15:30
User entered '28 Sep 2020 20:15'	System	29 Sep 2020 01:15:30

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 7'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:39

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-29T22:12:06', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1282dbd6-6341-4a30-a676-4df4cc67adf8'	System	30 Sep 2020 03:12:46
User entered 'None (0)'	System	30 Sep 2020 03:12:46

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:39

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-29T22:12:16', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1282dbd6-6341-4a30-a676-4df4cc67adf8'	System	30 Sep 2020 03:12:46
User entered 'No interference with activity (1)'	System	30 Sep 2020 03:12:46

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-29T22:12:18', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1282dbd6-6341-4a30-a676-4df4cc67adf8'	System	30 Sep 2020 03:12:46
User entered 'None (0)'	System	30 Sep 2020 03:12:46

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-29T22:12:20', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1282dbd6-6341-4a30-a676-4df4cc67adf8'	System	30 Sep 2020 03:12:46
User entered 'None (0)'	System	30 Sep 2020 03:12:46

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-29T22:12:22', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1282dbd6-6341-4a30-a676-4df4cc67adf8'	System	30 Sep 2020 03:12:46
User entered 'None (0)'	System	30 Sep 2020 03:12:46

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:39

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-29T22:12:27', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1282dbd6-6341-4a30-a676-4df4cc67adf8'	System	30 Sep 2020 03:12:46
User entered 'None (0)'	System	30 Sep 2020 03:12:46

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-29T22:12:35', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1282dbd6-6341-4a30-a676-4df4cc67adf8'	System	30 Sep 2020 03:12:46
User entered 'No (N)'	System	30 Sep 2020 03:12:46

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:39

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-29T22:12:43', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1282dbd6-6341-4a30-a676-4df4cc67adf8' User entered '29 Sep 2020 22:12'	System	30 Sep 2020 03:12:46
	System	30 Sep 2020 03:12:46

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 01:15:30
User entered 'Day 8'	System	29 Sep 2020 01:15:30

US3552191

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-30T21:06:17', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '6cc956df-2b79-4b39-8bf1-462559a187b3'	System	01 Oct 2020 02:06:29
User entered 'No interference with activity (1)'	System	01 Oct 2020 02:06:29

US3552191

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:36:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-30T21:06:27', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '6cc956df-2b79-4b39-8bf1-462559a187b3'	System	01 Oct 2020 02:06:29
User entered '30 Sep 2020 21:06'	System	01 Oct 2020 02:06:29

US3552191

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 01:15:30

US3552191

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 01:15:30

US3552191

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 03:12:46
User entered 'Day 9'	System	30 Sep 2020 03:12:46

US3552191

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-10-01T20:24:14', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'ac0c65ff-cde8-4f56-b277-a8d116c2308d'	System	02 Oct 2020 01:24:20
User entered 'None (0)'	System	02 Oct 2020 01:24:20

US3552191

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:36:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-10-01T20:24:18', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'ac0c65ff-cde8-4f56-b277-a8d116c2308d'	System	02 Oct 2020 01:24:20
User entered '01 Oct 2020 20:24'	System	02 Oct 2020 01:24:20

US3552191

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 03:12:46

US3552191

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 03:12:46

US3552191

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 01:14:53
User entered 'Day 8'	System	29 Sep 2020 01:14:53

US3552191

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-30T21:06:32', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '77861b4b-0ccd-4a06-9f10-d37c5820b7af'	System	01 Oct 2020 02:06:38
User entered 'No (N)'	System	01 Oct 2020 02:06:38

US3552191

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:36:39

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-30T21:06:35', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '77861b4b-0ccd-4a06-9f10-d37c5820b7af' User entered '30 Sep 2020 21:06'	System	01 Oct 2020 02:06:38
	System	01 Oct 2020 02:06:38

US3552191

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 01:14:53

US3552191

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 01:14:53

US3552191

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 03:12:46
User entered 'Day 9'	System	30 Sep 2020 03:12:46

US3552191

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-10-01T20:24:22', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'ea9e862a-4425-430d-a5cf-d38be9077f7d'	System	02 Oct 2020 01:24:27
User entered 'No (N)'	System	02 Oct 2020 01:24:27

US3552191

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:36:39

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-10-01T20:24:25', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'ea9e862a-4425-430d-a5cf-d38be9077f7d'	System	02 Oct 2020 01:24:27
User entered '01 Oct 2020 20:24'	System	02 Oct 2020 01:24:27

US3552191

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:36:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 03:12:46

US3552191

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:36:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 03:12:46

US3552191

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	30 Sep 2020 17:04:18

US3552191

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	30 Sep 2020 17:04:18

US3552191

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	30 Sep 2020 17:04:18

US3552191

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	30 Sep 2020 17:04:18

US3552191

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joan Siegner (b) (4)	07 Oct 2020 18:44:31

US3552191

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 18:44:31

US3552191

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joan Siegner (b) (4)	07 Oct 2020 18:44:43

US3552191

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '7 Oct 2020'	Joan Siegner (b) (4)	07 Oct 2020 18:44:43

US3552191

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Joan Siegner (b) (4)	07 Oct 2020 18:44:43

US3552191

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Joan Siegner (b) (4)	07 Oct 2020 18:44:43

US3552191

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:22:47

US3552191

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 15:22:47

US3552191

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:22:55

US3552191

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:22:55

US3552191

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:22:55

US3552191

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:22:55

US3552191

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:26:08

US3552191

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 19:26:08

US3552191

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:36:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:26:16

US3552191

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '19 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:26:16

US3552191

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:26:16

US3552191

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:36:39

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	19 Oct 2020 19:26:16

US3552191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:27:05

US3552191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:27:05

US3552191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:27:05

US3552191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 19:27:05

US3552191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:27:05

US3552191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:27:05

US3552191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:27:05

US3552191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:27:05

US3552191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 19:27:05

US3552191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:27:05

US3552191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 19:27:05

US3552191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:27:05

US3552191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 19:27:05

US3552191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:27:05

US3552191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 19:27:05

US3552191

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:27:11

US3552191

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '19 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:27:11

US3552191

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:27:23

US3552191

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '19 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:27:23

US3552191

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:39

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:25'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:27:23

US3552191

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 10:25'	System	19 Oct 2020 19:27:23

US3552191

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:14:52

US3552191

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 13:14:52

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 64'	System	26 Aug 2020 20:56:35

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-10-26T21:25:17', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'b5a4c9c6-8d75-4379-acc2-beb458871440'	System	27 Oct 2020 02:26:17
User entered 'Yes (Y)'	System	27 Oct 2020 02:26:17

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Have you been exposed to someone with 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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-10-26T21:25:23', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'b5a4c9c6-8d75-4379-acc2-beb458871440'	System	27 Oct 2020 02:26:17
User entered 'No (N)'	System	27 Oct 2020 02:26:17

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-10-26T21:25:29', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'b5a4c9c6-8d75-4379-acc2-beb458871440'	System	27 Oct 2020 02:26:17
User entered 'No (N)'	System	27 Oct 2020 02:26:17

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-10-26T21:25:38', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'b5a4c9c6-8d75-4379-acc2-beb458871440'	System	27 Oct 2020 02:26:17
User entered 'Yes (Y)'	System	27 Oct 2020 02:26:17

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Please 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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-10-26T21:25:51', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'b5a4c9c6-8d75-4379-acc2-beb458871440'	System	27 Oct 2020 02:26:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Oct 2020 02:26:17

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-10-26T21:26:08', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'b5a4c9c6-8d75-4379-acc2-beb458871440' User entered '26 Oct 2020 21:26:08'	System	27 Oct 2020 02:26:17
	System	27 Oct 2020 02:26:17

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:56:35
User entered '26 Oct 2020 00:01'	System	26 Aug 2020 20:56:35

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:56:35
User entered '30 Oct 2020 23:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 71'	System	26 Aug 2020 20:56:35

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-11-04T22:08:20', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '2fcb33e0-82d3-4ed8-aba3-c88dbf8073ec'	System	05 Nov 2020 04:08:55
User entered 'No (N)'	System	05 Nov 2020 04:08:55

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Have you been exposed to someone with 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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-11-04T22:08:27', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '2fcb33e0-82d3-4ed8-aba3-c88dbf8073ec'	System	05 Nov 2020 04:08:55
User entered 'No (N)'	System	05 Nov 2020 04:08:55

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-11-04T22:08:49', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '2fcb33e0-82d3-4ed8-aba3-c88dbf8073ec'	System	05 Nov 2020 04:08:55
User entered '04 Nov 2020 22:08:49'	System	05 Nov 2020 04:08:55

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:56:35
User entered '02 Nov 2020 00:01'	System	26 Aug 2020 20:56:35

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:56:35
User entered '06 Nov 2020 23:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 78'	System	26 Aug 2020 20:56:35

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-11-09T21:03:15', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'd958c541-a41b-4b3f-a565-b6a1d6e32aa1'	System	10 Nov 2020 03:03:31
User entered 'No (N)'	System	10 Nov 2020 03:03:31

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

Have you been exposed to someone with 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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-11-09T21:03:21', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'd958c541-a41b-4b3f-a565-b6a1d6e32aa1'	System	10 Nov 2020 03:03:31
User entered 'No (N)'	System	10 Nov 2020 03:03:31

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-11-09T21:03:28', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'd958c541-a41b-4b3f-a565-b6a1d6e32aa1'	System	10 Nov 2020 03:03:31
User entered '09 Nov 2020 21:03:28'	System	10 Nov 2020 03:03:31

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:56:35
User entered '09 Nov 2020 00:01'	System	26 Aug 2020 20:56:35

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:56:35
User entered '13 Nov 2020 23:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '23 Oct 2020 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '27 Oct 2020 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '30 Oct 2020 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '03 Nov 2020 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '06 Nov 2020 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '10 Nov 2020 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '13 Nov 2020 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '17 Nov 2020 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-11-24T09:55:45', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'bbf3025a-c4f0-4cc9-8e04-9b3a638f6f3f' User entered 'No (N)'	System	24 Nov 2020 15:55:58

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Have you been exposed to someone with 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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-11-24T09:55:41', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'bbf3025a-c4f0-4cc9-8e04-9b3a638f6f3f' User entered 'No (N)'	System	24 Nov 2020 15:55:58
	System	24 Nov 2020 15:55:58

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-11-24T09:55:56', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'bbf3025a-c4f0-4cc9-8e04-9b3a638f6f3f' User entered '24 Nov 2020 09:55:56'	System	24 Nov 2020 15:55:58
	System	24 Nov 2020 15:55:58

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '28 Oct 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '01 Nov 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:15:05

US3552191

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '18 Nov 2020'	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:15:05

US3552191

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4)	19 Nov 2020 13:15:05

US3552191

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:15:05

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:36:39

[Date of Contact](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	18 Nov 2020 21:58:02
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09OCT2020 and 12OCT2020 is reported under Illness Visits 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)	04 Nov 2020 09:41:04
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09OCT2020 and 12OCT2020 is reported under Illness Visits 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 'No folder available to enter results in EDC' (Site from DM).	Heather Douds (b) (4)	29 Oct 2020 13:59:52
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09OCT2020 and 12OCT2020 is reported under Illness Visits 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)	29 Oct 2020 07:18:39
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09OCT2020 and 2OCT2020 is reported under Illness Visits 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.' canceled (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 07:18:29
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09OCT2020 and 2OCT2020 is reported under Illness Visits 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)	29 Oct 2020 07:16:27
User entered '7 Oct 2020'	Mikayla Frye (b) (4)	08 Oct 2020 15:45:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:36:39

[Time of Contact](#)

Audit	User	Time (GMT)
User entered '12:39'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:45:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:36:39

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:39'	System	18 Nov 2020 21:58:02
User entered '7 Oct 2020 12:39'	System	08 Oct 2020 15:45:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:36:39

[Type of Contact](#)

Audit	User	Time (GMT)
User entered 'Safety Call (Safety Call)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:45:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:36:39

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:45:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:36:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:25:21
User entered 'Day 1 (Day 1)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:36:39

[Date](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	18 Nov 2020 21:58:25
User entered '2 Oct 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	08 Oct 2020 15:46:57
User entered '01 Oct 2020'	Mikayla Frye (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:36:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Heather Douds (b) (4)	09 Oct 2020 14:02:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:36:39

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:36:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:36:39

[Temperature](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:36:39

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:36:39

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:36:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:36:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:36:39

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:36:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:36:39

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:36:39

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:36:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:36:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:36:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:36:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:36:39

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:36:39

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:36:39

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:36:39

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:36:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:25:21
User entered 'Day 2 (Day 2)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:36:39

[Date](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:36:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Heather Douds (b) (4)	09 Oct 2020 14:02:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:36:39

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:36:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	08 Oct 2020 15:46:48

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:36:39

[Temperature](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:36:39

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:36:39

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:36:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:36:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:36:39

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:36:39

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:36:39

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:36:39

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:36:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:36:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:36:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:36:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:36:39

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:36:39

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:36:39

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:36:39

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:36:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:25:21
User entered 'Day 3 (Day 3)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:36:39

[Date](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:36:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Heather Douds (b) (4)	09 Oct 2020 14:02:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:36:39

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:36:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:36:39

[Temperature](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:36:39

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:36:39

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:36:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:36:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:36:39

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:36:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:36:39

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:36:39

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:36:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:36:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:36:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:36:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:36:39

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:36:39

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:36:39

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:36:39

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:36:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:25:21
User entered 'Day 5 (Day 5)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:36:39

[Date](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	18 Nov 2020 21:58:25
User entered '5 Oct 2020' reason for change: Data Entry Error	Heather Douds (b) (4)	28 Oct 2020 17:26:33
User entered '4 Oct 2020'	Mikayla Frye (b) (4)	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:36:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Heather Douds (b) (4)	09 Oct 2020 14:02:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:36:39

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:36:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:36:39

[Temperature](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:36:39

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:36:39

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:36:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:36:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:36:39

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:36:39

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:36:39

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:36:39

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:36:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:36:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:36:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:36:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:36:39

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:36:39

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:36:39

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:36:39

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:36:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:25:21
User entered 'Day 5 (Day 5)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:36:39

[Date](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	18 Nov 2020 21:58:25
User entered '6 Oct 2020'	Mikayla Frye (b) (4)	08 Oct 2020 15:49:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:36:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Heather Douds (b) (4)	09 Oct 2020 14:02:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:36:39

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:36:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	08 Oct 2020 15:49:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:36:39

[Temperature](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:36:39

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:36:39

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:36:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:36:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:36:39

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:36:39

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:36:39

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:36:39

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:36:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:36:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:36:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:36:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:36:39

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:36:39

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:36:39

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:36:39

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:36:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:25:21
User entered 'Day 6 (Day 6)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:36:39

[Date](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	18 Nov 2020 21:58:25
User entered '7 Oct 2020'	Mikayla Frye (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:36:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Heather Douds (b) (4)	09 Oct 2020 14:02:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:36:39

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:36:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:36:39

[Temperature](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:36:39

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:36:39

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:36:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:36:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:36:39

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:36:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:36:39

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:36:39

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:36:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:36:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:36:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:36:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:36:39

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:36:39

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:36:39

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:36:39

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:36:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:25:21
User entered 'Day 8 (Day 8)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:36:39

[Date](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	18 Nov 2020 21:58:25
User entered '8 Oct 2020'	Mikayla Frye (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:36:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:36:39

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '94'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:36:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:36:39

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.3' F	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:36:39

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:36:39

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:36:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:36:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:36:39

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:36:39

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:36:39

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:36:39

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:36:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:36:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:36:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:36:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:36:39

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:36:39

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:36:39

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:36:39

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:36:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)' reason for change:	Heather Douds (b) (4)	28 Oct 2020 17:25:21
Data Entry Error	(b) (4)	
User entered 'Day 9 (Day 9)'	Heather Douds (b) (4)	09 Oct 2020 14:02:31
	(b) (4)	

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:36:39

[Date](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	18 Nov 2020 21:58:25
User entered '9 Oct 2020'	Heather Douds (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:36:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:36:39

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '95'	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:36:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:36:39

[Temperature](#)

Audit	User	Time (GMT)
User entered '99' F	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:36:39

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:36:39

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:36:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:36:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:36:39

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:36:39

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:36:39

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:36:39

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:36:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:36:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:36:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:36:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:36:39

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:36:39

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:36:39

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:36:39

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:36:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)' reason for change:	Heather Douds (b) (4)	28 Oct 2020 17:25:21
Data Entry Error	(b) (4)	
User entered 'Day 10 (Day 10)'	Stanley Dublin (b) (4)	12 Oct 2020 15:37:38
	(b) (4)	

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:36:39

[Date](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:36:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:36:39

[O2 Saturation](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: it appears subject as <= 93% saturation recorded in Symptom Log Days 9 and 10 yet there is no Covid Severity Assessment form completed. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 16:46:44
Query 'Per CDM: it appears subject as <= 93% saturation recorded in Symptom Log Days 9 and 10 yet there is no Covid Severity Assessment form completed. Please reconcile or clarify.' answered with 'Not COVID positive. ' (Site from DM).	Cassandra Zehenny (b) (4)	05 Nov 2020 15:40:59
User opened query 'Per CDM: it appears subject as <= 93% saturation recorded in Symptom Log Days 9 and 10 yet there is no Covid Severity Assessment form completed. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 20:10:25
User entered '88'	Stanley Doublin (b) (4)	12 Oct 2020 15:37:38

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:36:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Oct 2020 15:37:38

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:36:39

[Temperature](#)

Audit	User	Time (GMT)
User entered '98' F	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:36:39

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:36:39

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:36:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:36:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:36:39

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:36:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:36:39

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:36:39

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:36:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:36:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:36:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:36:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:36:39

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:36:39

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:36:39

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:36:39

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:36:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)' reason for change:	Heather Douds (b) (4)	28 Oct 2020 17:25:21
Data Entry Error	(b) (4)	
User entered 'Day 11 (Day 11)'	Stanley Dublin (b) (4)	12 Oct 2020 15:39:08
	(b) (4)	

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:36:39

[Date](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:36:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:36:39

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '91'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:36:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Oct 2020 15:39:08

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:36:39

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.8' F	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:36:39

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:36:39

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:36:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:36:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:36:39

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:36:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:36:39

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:36:39

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:36:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:36:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:36:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:36:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:36:39

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:36:39

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:36:39

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:36:39

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:36:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 13 (Day 13)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:25:21
User entered 'Day 16 (Day 16)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:22:11
User entered 'Day 12 (Day 12)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:36:39

[Date](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:36:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:36:39

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '95'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:36:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Oct 2020 15:39:56

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:36:39

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.5' F	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:36:39

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:36:39

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:36:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:36:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:36:39

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:36:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:36:39

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:36:39

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:36:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:36:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:36:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:36:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:36:39

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:36:39

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:36:39

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:36:39

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:36:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:25:21
User entered 'Day 16 (Day 16)'	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:22:11

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:36:39

[Date](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 17:25:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 17:25:21
User entered '30 Sep 2020' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:25:21
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 17:22:11
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:22:11

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:36:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered '0'	Heather Douds (b) (4)	28 Oct 2020 17:22:11

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:36:39

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered empty.	Heather Douds (b) (4)	28 Oct 2020 17:22:11

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:36:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	28 Oct 2020 17:25:21
User entered empty.	System	28 Oct 2020 17:22:11

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:36:39

[Temperature](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered empty.	Heather Douds (b) (4)	28 Oct 2020 17:22:11

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:36:39

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: New Information	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered empty.	Heather Douds (b) (4)	28 Oct 2020 17:22:11

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:36:39

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered empty.	Heather Douds (b) (4)	28 Oct 2020 17:22:11

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:36:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)' reason for change: Data Entry Error	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered empty.	Heather Douds (b) (4)	28 Oct 2020 17:22:11

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:36:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered empty.	Heather Douds (b) (4)	28 Oct 2020 17:22:11

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:36:39

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered empty.	Heather Douds (b) (4)	28 Oct 2020 17:22:11

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:36:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered empty.	Heather Douds (b) (4)	28 Oct 2020 17:22:11

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:36:39

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered empty.	Heather Douds (b) (4)	28 Oct 2020 17:22:11

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:36:39

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered empty.	Heather Douds (b) (4)	28 Oct 2020 17:22:11

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:36:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered empty.	Heather Douds (b) (4)	28 Oct 2020 17:22:11

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:36:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered empty.	Heather Douds (b) (4)	28 Oct 2020 17:22:11

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:36:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered empty.	Heather Douds (b) (4)	28 Oct 2020 17:22:11

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:36:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered empty.	Heather Douds (b) (4)	28 Oct 2020 17:22:11

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:36:39

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered empty.	Heather Douds (b) (4)	28 Oct 2020 17:22:11

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:36:39

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered empty.	Heather Douds (b) (4)	28 Oct 2020 17:22:11

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:36:39

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered empty.	Heather Douds (b) (4)	28 Oct 2020 17:22:11

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:36:39

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered empty.	Heather Douds (b) (4)	28 Oct 2020 17:22:11

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:36:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:26:33

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:36:39

[Date](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	18 Nov 2020 21:58:25
User entered '1 Oct 2020'	Heather Douds (b) (4)	28 Oct 2020 17:26:33

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:36:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:26:33

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:36:39

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:26:33

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:36:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	28 Oct 2020 17:26:33

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:36:39

[Temperature](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:26:33

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:36:39

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:26:33

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:36:39

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:26:33

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:36:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:26:33

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:36:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:26:33

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:36:39

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:26:33

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:36:39

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:26:33

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:36:39

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:26:33

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:36:39

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:26:33

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:36:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:26:33

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:36:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:26:33

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:36:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:26:33

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:36:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:26:33

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:36:39

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:26:33

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:36:39

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:26:33

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:36:39

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:26:33

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:36:39

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:26:33

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:36:39

[Date of Visit](#)

Audit	User	Time (GMT)
User entered '8 Oct 2020'	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:01:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:36:39

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:01:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:36:39

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 17:45:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 17:45:41
User entered 'No (N)' reason for change: New Information	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 17:45:41
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 14:01:03
User entered empty.	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:01:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:36:39

[Date of Test](#)

Audit	User	Time (GMT)
User entered '8 Oct 2020'	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:01:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:36:39

[Type of Test Performed](#)

Audit	User	Time (GMT)
User entered 'Nasopharyngeal Swab (NasopharyngealHeather Douds Swab)'	(b) (4)	09 Oct 2020 14:01:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:36:39

[Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:01:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:36:39

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:01:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:36:39

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
User entered empty.	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:01:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:36:39

[CLIA Certified?](#)

Audit	User	Time (GMT)
User entered empty.	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:01:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:36:39

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Oct 2020 17:45:41

US3552191

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:36:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

US3552191

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:36:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

US3552191

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:36:39

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:22:46
User entered '9 Oct 2020'	Stanley Dublin (b) (4)	29 Oct 2020 18:21:36

US3552191

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:36:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

US3552191

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:36:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

US3552191

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:36:39

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

US3552191

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:36:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

US3552191

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:36:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

US3552191

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:36:39

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

US3552191

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:36:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

US3552191

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:36:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

US3552191

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:36:39

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

US3552191

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:36:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

US3552191

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:36:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

US3552191

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:36:39

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

US3552191

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:36:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

US3552191

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:36:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

US3552191

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:36:39

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

US3552191

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:36:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

US3552191

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:36:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

US3552191

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:36:39

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

US3552191

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:36:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:15:21

US3552191

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '08 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:22:16
User entered '8 Oct 2020'	Stanley Dublin (b) (4)	29 Oct 2020 18:15:21

US3552191

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered 'Home (Home)'	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:15:21

US3552191

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:36:39

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	29 Oct 2020 18:15:21

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:16:00

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCG, Date should be recorded in (dd MMM yyyy) format. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 09:17:33
Query 'Per CDM: Per CCG, Date should be recorded in (dd MMM yyyy) format. Please review and update accordingly. ' answered with 'resolved' (Site from DM).	Cassandra Zehenny (b) (4)	09 Nov 2020 15:24:09
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4)	09 Nov 2020 15:23:58
User opened query 'Per CDM: Per CCG, Date should be recorded in (dd MMM yyyy) format. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 04:06:36
User entered '8 Oct 2020'	Stanley Dublin (b) (4)	29 Oct 2020 18:16:00

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '08:30'	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:16:00

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '08 Oct 2020 08:30'	System	09 Nov 2020 15:23:58
User entered '8 Oct 2020 08:30'	System	29 Oct 2020 18:16:00

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User closed query 'Per CDM: As per CCG: Data is required, please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 04:25:58
Query 'Per CDM: As per CCG: Data is required, please review and update accordingly. ' answered with 'Unable to be done at time of visit, data unavailable' (Site from DM).	Cassandra Zehenny (b) (4)	09 Nov 2020 15:24:02
User opened query 'Per CDM: As per CCG: Data is required, please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 04:06:04
User entered missing code ND - Not Done.	Stanley Doublin (b) (4)	29 Oct 2020 18:16:00
DataPoint set to visible.	(b) (4) System	29 Oct 2020 18:15:21

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

Weight (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM: As per CCG: Data is required, please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 04:25:56
Query 'Per CDM: As per CCG: Data is required, please review and update accordingly.' answered with 'Unable to be done at time of visit, data unavailable' (Site from DM).	Cassandra Zehenny (b) (4)	09 Nov 2020 15:24:05
User opened query 'Per CDM: As per CCG: Data is required, please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 04:06:14
User entered missing code ND - Not Done.	Stanley Doublin (b) (4)	29 Oct 2020 18:16:00
DataPoint set to visible.	(b) (4) System	29 Oct 2020 18:15:21

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.3' F	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:16:00

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:16:00

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:16:00

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '111'	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:16:00

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Oct 2020 18:16:00

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '20'	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:16:00

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Oct 2020 18:16:00

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '128'	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:16:00

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Oct 2020 18:16:00

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '80'	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:16:00

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Oct 2020 18:16:00

US3552191

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:16:49

US3552191

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:16:49

US3552191

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:36:39

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 18:17:18

US3552191

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:36:39

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:22:39
User entered '8 Oct 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4)	29 Oct 2020 18:17:43
User entered empty.	Stanley Doublin (b) (4)	29 Oct 2020 18:17:18

US3552191

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:36:39

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:42
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Oct 2020 17:26:02

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:25:52
Query 'Patient reported elevated hemoglobin on 06Oct. Please consider capturing this as an AE. ' canceled (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 14:25:05
User opened query 'Patient reported elevated hemoglobin on 06Oct. Please consider capturing this as an AE. ' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 14:13:52
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 17:27:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 17:27:52
Data point term sent to Coder	System	02 Oct 2020 17:27:21
User entered 'fatigue'	Stanley Doublin (b) (4)	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:25:53
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:25:55
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:25:56
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:25:58
User entered '24 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:26:00
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 17:30:50
User entered '18:42' reason for change: Data Entry Error	Stanley Doublin (b) (4)	02 Oct 2020 17:30:50
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 17:27:13
User entered empty.	Stanley Doublin (b) (4)	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 18:42'	System	02 Oct 2020 17:30:50
User entered empty.	System	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
DataPoint Un-verified.	Joan Siegner (b) (4)	11 Nov 2020 17:31:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Joan Siegner (b) (4)	11 Nov 2020 17:31:42
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:26:02
User entered 'No (N)'	Stanley Doublin (b) (4)	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
DataPoint Un-verified.	Joan Siegner (b) (4)	11 Nov 2020 17:31:42
User entered empty; reason for change Data Entry Error	Joan Siegner (b) (4)	11 Nov 2020 17:31:42
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:26:03
User entered '30 Sep 2020'	Stanley Doublin (b) (4)	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Nov 2020 17:31:42
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:26:04
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 11:35:37
Query 'Data is required. Please provide.' answered with 'exact time is unknown' (Site from System).	Stanley Doublin (b) (4)	02 Oct 2020 17:30:46
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 17:27:13
User entered empty.	Stanley Doublin (b) (4)	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:26:06
User entered 'Grade 1/Mild (Grade 1/Mild)'	Stanley Doublin (b) (4) (b) (4)	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:26:08
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:26:10
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:26:11
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:26:13
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:26:15
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:26:17
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:26:18
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:26:20
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:26:22
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:26:24
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:26:25
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:26:27
User entered 'Related (RELATED)'	Stanley Doublin (b) (4) (b) (4)	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:26:28
User entered 'Not Related (NOT RELATED)'	Stanley Doublin (b) (4) (b) (4)	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Stanley Dublin (b) (4)	23 Nov 2020 17:39:19
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Stanley Dublin (b) (4)	23 Nov 2020 17:39:19
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:26:30
User entered 'None (NONE)'	Stanley Dublin (b) (4)	02 Oct 2020 17:27:13
	(b) (4)	

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:26:32
User entered '1'	Stanley Doublin (b) (4) (b) (4)	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:26:33
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:26:35
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
DataPoint Un-verified.	Joan Siegner (b) (4)	11 Nov 2020 17:31:42
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Joan Siegner (b) (4)	11 Nov 2020 17:31:42
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:26:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Stanley Dublin (b) (4)	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:26:38
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:26:39
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:36:39

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 13:45:12
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 15:23:16
User entered 'USA-US089-2020-mRNA-1273-P301000009'	(b) (4), (b) (6)	13 Oct 2020 15:23:12

US3552191

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:36:39

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 13:45:14
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Ankle edema - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 23:59:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 23:59:37
Data point term sent to Coder	System	08 Oct 2020 19:05:28
User entered 'bilateral ankle edema'	Stanley Doublin (b) (4) (b) (4)	08 Oct 2020 19:04:47

US3552191

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:36:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 01:38:37
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	08 Oct 2020 19:04:47

US3552191

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:36:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 01:38:33
User closed query 'BILATERAL ANKLE EDEMA is not considered solicited AR per protocol . Please consider updating to "no". Thank you ' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 15:26:38
Query 'BILATERAL ANKLE EDEMA is not considered solicited AR per protocol . Please consider updating to "no". Thank you ' answered with 'corrected' (Site from CRA).	Joan Siegner (b) (4)	15 Oct 2020 15:18:29
User entered 'No (N)' reason for change: Data Entry Error	Joan Siegner (b) (4)	15 Oct 2020 15:18:22
User opened query 'BILATERAL ANKLE EDEMA is not considered solicited AR per protocol . Please consider updating to "no". Thank you ' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 13:47:18
User entered 'Yes (Y)'	Stanley Dublin (b) (4)	08 Oct 2020 19:04:47

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 13:45:02
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	08 Oct 2020 19:04:47

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Folder: Adverse Events

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:22:37
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	09 Nov 2020 15:26:01
User entered '06 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 15:26:01
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 01:39:01
User closed query 'Thank you for your response. Please confirm SAE start date. ' (Site from CRA).	(b) (4), (b) (6)	18 Oct 2020 01:19:54
Query 'Thank you for your response. Please confirm SAE start date. ' answered with 'Start date accurate as entered' (Site from CRA).	Heather Douds (b) (4)	15 Oct 2020 15:34:04
User opened query 'Thank you for your response. Please confirm SAE start date. ' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 15:29:13
User closed query 'Since subject was hospitalized for one day to rule out heart failure , please consider updating SAE dates to hospitalization dates 09Oct-10Oct. Per Clinical summary, discharge diagnosis is Peripheral Edema - please consider updating SAE term. And Bilateral ankle edema please consider capturing as an AE.' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 15:29:13
Query 'Since subject was hospitalized for one day to rule out heart failure , please consider updating SAE dates to hospitalization dates 09Oct-10Oct. Per Clinical summary, discharge diagnosis is Peripheral Edema - please consider updating SAE term. And Bilateral ankle edema please consider capturing as an AE.' answered with 'corrected' (Site from CRA).	Joan Siegner (b) (4)	15 Oct 2020 15:19:45
User opened query 'Since subject was hospitalized for one day to rule out heart failure , please consider updating SAE dates to hospitalization dates 09Oct-10Oct. Per Clinical summary, discharge diagnosis is Peripheral Edema - please consider updating SAE term. And Bilateral ankle edema please consider capturing as an AE.' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 15:06:04
DataPoint Un-verified.	(b) (4), (b) (6)	15 Oct 2020 15:05:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 13:45:00

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:36:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '6 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	08 Oct 2020 19:04:47

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:36:39

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 01:39:12
User entered empty.	Stanley Doublin (b) (4) (b) (4)	08 Oct 2020 19:04:47

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:36:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 19:04:47

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Folder: Adverse Events

Form: Adverse Events (4)

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:59:35
DataPoint Un-verified.	Stanley Dublin (b) (4)	19 Nov 2020 13:19:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	19 Nov 2020 13:19:32
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:30:01
Query 'Per SC day 50,14Oct swollen ankles improving. Please consider adding stop date to SAE and capture AE swollen ankles as a separate entry. ' canceled (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 17:30:00
User opened query 'Per SC day 50,14Oct swollen ankles improving. Please consider adding stop date to SAE and capture AE swollen ankles as a separate entry. ' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 17:00:43
User entered 'Yes (Y)'	Stanley Dublin (b) (4)	08 Oct 2020 19:04:47

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Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:36:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:59:36
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	19 Nov 2020 13:25:45
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	19 Nov 2020 13:25:45
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	19 Nov 2020 13:19:32
DataPoint Un-verified.	Stanley Dublin (b) (4)	19 Nov 2020 13:19:32
User entered '31 Oct 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	19 Nov 2020 13:19:32
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:30:03
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 17:21:02
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'ongoing at this time, will update when when appropriate' (Site from Safety).	Heather Douds (b) (4)	22 Oct 2020 16:08:40
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 17:43:35
User entered empty.	Stanley Dublin (b) (4)	08 Oct 2020 19:04:47

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Form: Adverse Events (4)

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End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:30:05
User entered empty.	Stanley Doublin (b) (4) (b) (4)	08 Oct 2020 19:04:47

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:36:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'SAE#4 PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' canceled (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 23:23:08
User opened query 'SAE#4 PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 17:27:48
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' canceled (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 17:27:02
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 12:53:55
User entered empty.	System	08 Oct 2020 19:04:47

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Folder: Adverse Events

Form: Adverse Events (4)

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:30:07
User closed query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 17:21:12
Query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' answered with 'Resolved per query request' (Site from Safety).	Cassandra Zehenny (b) (4)	21 Oct 2020 19:23:43
User entered 'Grade 4 (Grade 4)' reason for change: Per Query Resolution	(b) (4)	21 Oct 2020 19:22:30
User opened query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 17:44:41
DataPoint Un-verified.	(b) (4), (b) (6)	15 Oct 2020 14:33:08
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:25:47
User entered 'Grade 1/Mild (Grade 1/Mild)'	Stanley Doublin (b) (4)	08 Oct 2020 19:04:47

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Folder: Adverse Events

Form: Adverse Events (4)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'Thank you for your response. Please provide site awareness date. ' (Site from CRA).	(b) (4), (b) (6)	18 Oct 2020 01:22:50
Query 'Thank you for your response. Please provide site awareness date. ' answered with 'Start date accurate as entered; subject was seen for illness visit 10/8 and notified site of hospitalization on 10/10, entered as SAE for r/o congestive heart failure on 10/11; closed out SAE for congestive heart failure on 10/12 once medical records were obtained as this was not accurate per medical records. Updated AE of SOB on exertion and bilateral ankle edema to SAEs on 10/12 to reflect hospitalization. ' (Site from CRA).	Heather Douds (b) (4) (b) (4)	15 Oct 2020 15:38:01
User opened query 'Thank you for your response. Please provide site awareness date. ' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 15:27:11
User closed query 'Hospitalization date is 09Oct2020, and event is reported as SAE on 12Oct. Please provide the date of awareness. ' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 15:27:11
Query 'Hospitalization date is 09Oct2020, and event is reported as SAE on 12Oct. Please provide the date of awareness. ' answered with 'done' (Site from CRA).	Joan Siegner (b) (4)	15 Oct 2020 15:20:11
User opened query 'Hospitalization date is 09Oct2020, and event is reported as SAE on 12Oct. Please provide the date of awareness. ' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 15:07:12
Query 'Event is reported as SAE on 12Oct2020. Start date is 06Oct2020. Please indicate the date of awareness. If SAE is not reported within 24 hrs of awareness date, this should be captured as PD. ' canceled (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 15:06:15
User opened query 'Event is reported as SAE on 12Oct2020. Start date is 06Oct2020. Please indicate the date of awareness. If SAE is not reported within 24 hrs of awareness date, this should be captured as PD. ' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 14:38:45
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:16:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Joan Siegner (b) (4)	12 Oct 2020 18:43:35

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	08 Oct 2020 19:04:47

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:36:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:16:16
User entered '0'	Stanley Doublin (b) (4) (b) (4)	08 Oct 2020 19:04:47

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Folder: Adverse Events

Form: Adverse Events (4)

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:16:18
User entered '0'	Stanley Doublin (b) (4) (b) (4)	08 Oct 2020 19:04:47

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:36:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:16:14
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		12 Oct 2020 18:43:56
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		12 Oct 2020 18:43:56
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	12 Oct 2020 18:43:35
User entered '1' reason for change: Data Entry Error	Joan Siegner (b) (4)	12 Oct 2020 18:43:35
User entered '0'	Stanley Dublin (b) (4)	08 Oct 2020 19:04:47

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:36:39

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:22:14
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	09 Nov 2020 15:26:01
User entered '09 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	09 Nov 2020 15:26:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 14:16:07
User entered '9 Oct 2020' reason for change: Data Entry Error	Joan Siegner (b) (4)	12 Oct 2020 18:43:35
User entered empty.	Stanley Doublin (b) (4)	08 Oct 2020 19:04:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:36:39

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:16:08
User entered '10 Oct 2020' reason for change: Data Entry Error	Joan Siegner (b) (4)	12 Oct 2020 18:43:35
User entered empty.	Stanley Dublin (b) (4)	08 Oct 2020 19:04:47

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Folder: Adverse Events

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:16:11
User entered 'No (N)' reason for change: Data Entry Error	Joan Siegner (b) (4)	12 Oct 2020 18:43:56
User entered empty.	Stanley Dublin (b) (4)	08 Oct 2020 19:04:47

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Folder: Adverse Events

Form: Adverse Events (4)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:25:51
User entered empty.	Stanley Doublin (b) (4) (b) (4)	08 Oct 2020 19:04:47

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Folder: Adverse Events

Form: Adverse Events (4)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:30:10
User entered '0'	Stanley Doublin (b) (4) (b) (4)	08 Oct 2020 19:04:47

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Folder: Adverse Events

Form: Adverse Events (4)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:25:52
User entered '0'	Stanley Doublin (b) (4) (b) (4)	08 Oct 2020 19:04:47

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 01:39:22
User entered '0'	Stanley Dublin (b) (4) (b) (4)	08 Oct 2020 19:04:47

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the investigator's rationale for assessing this event as related to study drug.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 17:21:19
Query 'PV Query: Please provide the investigator's rationale for assessing this event as related to study drug.' answered with 'No other etiology has been discovered at this time.' (Site from Safety).	Cassandra Zehenny (b) (4)	21 Oct 2020 19:23:28
User opened query 'PV Query: Please provide the investigator's rationale for assessing this event as related to study drug.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 17:43:15
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:25:54
User entered 'Related (RELATED)'	Stanley Doublin (b) (4)	08 Oct 2020 19:04:47

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Folder: Adverse Events

Form: Adverse Events (4)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:16:03
User entered 'Not Related (NOT RELATED)'	Stanley Doublin (b) (4) (b) (4)	08 Oct 2020 19:04:47

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Folder: Adverse Events

Form: Adverse Events (4)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:16:01
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Joan Siegner (b) (4)	12 Oct 2020 18:43:35
User entered 'None (NONE)'	Stanley Dublin (b) (4)	08 Oct 2020 19:04:47

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Folder: Adverse Events

Form: Adverse Events (4)

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None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:15:59
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).		12 Oct 2020 18:44:10
User entered '0' reason for change: Data Entry Error Joan Siegner	(b) (4)	12 Oct 2020 18:44:10
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	12 Oct 2020 18:43:35
User entered '1'	Stanley Dublin (b) (4)	08 Oct 2020 19:04:47

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Folder: Adverse Events

Form: Adverse Events (4)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:15:55
User entered '1' reason for change: Data Entry Error	Joan Siegner (b) (4)	12 Oct 2020 18:43:35
User entered '0'	Stanley Dublin (b) (4)	08 Oct 2020 19:04:47

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Folder: Adverse Events

Form: Adverse Events (4)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:15:54
User entered '0'	Stanley Dublin (b) (4) (b) (4)	08 Oct 2020 19:04:47

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:36:39

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:59:41
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 21:47:16
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'has recovered/resolved' (Site from Safety).	Stanley Doublin (b) (4)	19 Nov 2020 13:28:52
DataPoint Un-verified.	Stanley Doublin (b) (4)	19 Nov 2020 13:25:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	19 Nov 2020 13:25:45
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 17:43:55
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:15:52
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Stanley Doublin (b) (4)	08 Oct 2020 19:04:47

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:15:50
User entered empty.	Stanley Doublin (b) (4) (b) (4)	08 Oct 2020 19:04:47

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:59:43
DataPoint Un-verified.	Heather Douds (b) (4)	23 Nov 2020 19:58:29
User entered 'SUBJECT NOTIFIED SITE 07OCT2020 OF SHORTNESS OF BREATH ON EXERTION, FATIGUE AND SWOLLEN ANKLES. SITE SENT HOME HEALTH NURSES TO HER HOME ON 08OCT2020 TO DO ILLNESS VISIT AND ADVISED HER TO NOTIFY HER PCP OF SYMPTOMS. SUBJECT SAW PCP ON 09OCT2020 AND WAS SENT TO ER FOR CARDIAC EVALUATION. WAS ADMITTED OVERNIGHT TO HOSPITAL AND TREATED WITH IVP LASIX AND DIURESED. HAD LAB WORK, ECG AND CT OF CHEST. DISCHARGED THE NEXT DAY AND HAD ECHOCARDIOGRAM THE AM OF 12OCT2020. HOSPITAL MEDICAL RECORDS RECEIVED AND SENT TO SPONSOR. PER CARDIOLOGIST'S OFFICE, ECHO NEGATIVE. X RAY "WITHOUT SIGNIFICANT OR ACUTE FINDINGS," CHEST CT "NO EVIDENCE OF PE," ECG "SINUS TACHYCARDIA, NO EVIDENCE OF INJURY PATTERN"; PCP PRESCRIBED ATENOLOL FOR SUBJECT, STARTED ON 30OCT2020. AS OF 11/18 PHONE CALL, SUBJECT REPORTS THAT IT HAS RESOLVED.'	Heather Douds (b) (4)	23 Nov 2020 19:58:29
reason for change: Per Query Resolution		
User closed query 'PV Query: Please enter start date for concomitant medication of atenolol. ' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 19:06:25
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:22:09
Query 'PV Query: Please enter start date for concomitant medication of atenolol. ' answered with 'updated' (Site from Safety).	Cassandra Zehenny (b) (4)	09 Nov 2020 15:33:24
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	09 Nov 2020 15:33:19

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT NOTIFIED SITE 07OCT2020 OF SHORTNESS OF BREATH ON EXERTION, FATIGUE AND SWOLLEN ANKLES. SITE SENT HOME HEALTH NURSES TO HER HOME ON 08OCT2020 TO DO ILLNESS VISIT AND ADVISED HER TO NOTIFY HER PCP OF SYMPTOMS. SUBJECT SAW PCP ON 09OCT2020 AND WAS SENT TO ER FOR CARDIAC EVALUATION. WAS ADMITTED OVERNIGHT TO HOSPITAL AND TREATED WITH IVP LASIX AND DIURESED. HAD LAB WORK, ECG AND CT OF CHEST. DISCHARGED THE NEXT DAY AND HAD ECHOCARDIOGRAM THE AM OF 12OCT2020. HOSPITAL MEDICAL RECORDS RECEIVED AND SENT TO SPONSOR. PER CARDIOLOGIST'S OFFICE, ECHO NEGATIVE. X RAY "WITHOUT SIGNIFICANT OR ACUTE FINDINGS," CHEST CT "NO EVIDENCE OF PE," ECG "SINUS TACHYCARDIA, NO EVIDENCE OF INJURY PATTERN"; PCP prescribed atenolol for subject, started on 30Oct2020' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	09 Nov 2020 15:33:19
User opened query 'PV Query: Please enter start date for concomitant medication of atenolol. ' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 17:28:07
User closed query 'PV Query: Please provide a summary of the echocardiogram results when available.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 16:18:41
Query 'PV Query: Please provide a summary of the echocardiogram results when available.' answered with 'see narrative; essentially negative' (Site from Safety).	Joan Siegner (b) (4)	30 Oct 2020 17:06:32
User opened query 'PV Query: Please provide a summary of the echocardiogram results when available.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 12:56:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:30:13
DataPoint Un-verified.	Heather Douds (b) (4)	15 Oct 2020 16:06:22

US3552191

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:36:39

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT NOTIFIED SITE 07OCT2020 OF SHORTNESS OF BREATH ON EXERTION, FATIGUE AND SWOLLEN ANKLES. SITE SENT HOME HEALTH NURSES TO HER HOME ON 08OCT2020 TO DO ILLNESS VISIT AND ADVISED HER TO NOTIFY HER PCP OF SYMPTOMS. SUBJECT SAW PCP ON 09OCT2020 AND WAS SENT TO ER FOR CARDIAC EVALUATION. WAS ADMITTED OVERNIGHT TO HOSPITAL AND TREATED WITH IVP LASIX AND DIURESED. HAD LAB WORK, ECG AND CT OF CHEST. DISCHARGED THE NEXT DAY AND HAD ECHOCARDIOGRAM THE AM OF 12OCT2020. HOSPITAL MEDICAL RECORDS RECEIVED AND SENT TO SPONSOR. Per cardiologist's office, echo negative. X ray "without significant or acute findings," Chest CT "no evidence of PE," Ecg "sinus tachycardia, no evidence of injury pattern"' reason for change: Per Query Resolution DataPoint Verified.	Heather Douds (b) (4) (b) (4)	15 Oct 2020 16:06:22
	(b) (4), (b) (6)	15 Oct 2020 14:15:49
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	12 Oct 2020 18:47:53
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	12 Oct 2020 18:47:53
User entered 'Subject notified site 07OCT2020 of shortness of breath on exertion, fatigue and swollen ankles. Site sent home health nurses to her home on 08OCT2020 to do illness visit and advised her to notify her PCP of symptoms. Subject saw PCP on 09OCT2020 and was sent to ER for cardiac evaluation. Was admitted overnight to hospital and treated with IVP lasix and diuresed. Had lab work, ECG and CT of chest. Discharged the next day and had echocardiogram the AM of 12OCT2020. Hospital medical records received and sent to sponsor.' reason for change: Data Entry Error	Joan Siegner (b) (4)	12 Oct 2020 18:47:53

US3552191

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:36:39

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	12 Oct 2020 18:43:35
User entered empty.	Stanley Dublin (b) (4) (b) (4)	08 Oct 2020 19:04:47

US3552191

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:36:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 18:43:35
User entered '0'	System	08 Oct 2020 19:04:47

US3552191

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:36:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Oct 2020 19:04:47

US3552191

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:36:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Oct 2020 18:43:56

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:06
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 17:39:13
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:13
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 19:25:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 19:25:22
Data point term sent to Coder	System	09 Oct 2020 19:24:46
User entered 'cough'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:10

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:15
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 17:39:11
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:15
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:10

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:13
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:10

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:11
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:10

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:08
User entered '08 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 15:28:03
User entered '8 Oct 2020'	Mikayla Frye (b) (4)	09 Oct 2020 19:24:10

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:10

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 19:24:10

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:10

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '08 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 15:28:03
User entered '8 Oct 2020'	Mikayla Frye (b) (4)	09 Oct 2020 19:24:10

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:10

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 19:24:10

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Grade 1/Mild (Grade 1/Mild)'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:10

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:10

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:10

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:10

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:10

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:10

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:10

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:10

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:10

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:10

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:10

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Related (RELATED)'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Not Related (NOT RELATED)'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:10

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Stanley Dublin (b) (4)	23 Nov 2020 17:41:13
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Stanley Dublin (b) (4)	23 Nov 2020 17:41:13
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'None (NONE)'	Mikayla Frye (b) (4)	09 Oct 2020 19:24:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '1'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:10

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:10

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:10

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:10

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:10

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:10

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Oct 2020 19:24:10

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:36:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Oct 2020 19:24:10

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:13:11
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 19:26:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 19:26:28
Data point term sent to Coder	System	09 Oct 2020 19:25:47
User entered 'headache'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:13:13
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:13:14
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:13:16
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:13:17
User entered '08 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 15:28:16
User entered '8 Oct 2020'	Mikayla Frye (b) (4)	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:13:20
User entered empty.	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:13:21
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:13:23
User entered '08 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 15:28:16
User entered '8 Oct 2020'	Mikayla Frye (b) (4)	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Grade 1/Mild (Grade 1/Mild)'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Related (RELATED)'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Not Related (NOT RELATED)'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Stanley Dublin (b) (4)	23 Nov 2020 17:41:21
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Stanley Dublin (b) (4)	23 Nov 2020 17:41:21
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'None (NONE)'	Mikayla Frye (b) (4)	09 Oct 2020 19:24:50
	(b) (4)	

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '1'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:36:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:13:29
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Oropharyngeal pain, LLT: Sore throat - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 19:26:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 19:26:28
Data point term sent to Coder	System	09 Oct 2020 19:25:52
User entered 'sore throat'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:13:30
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:13:32
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:13:34
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:13:35
User entered '08 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 15:28:26
User entered '8 Oct 2020'	Mikayla Frye (b) (4)	09 Oct 2020 19:25:25

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:13:37
User entered empty.	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 19:25:25

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:13:38
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:13:40
User entered '08 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 15:28:26
User entered '8 Oct 2020'	Mikayla Frye (b) (4)	09 Oct 2020 19:25:25

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 19:25:25

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Grade 1/Mild (Grade 1/Mild)'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Related (RELATED)'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Not Related (NOT RELATED)'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Stanley Dublin (b) (4)	23 Nov 2020 17:41:32
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Stanley Dublin (b) (4)	23 Nov 2020 17:41:32
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'None (NONE)'	Mikayla Frye (b) (4)	09 Oct 2020 19:25:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '1'	Mikayla Frye (b) (4)	09 Oct 2020 19:25:25
	(b) (4)	

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Oct 2020 19:25:25

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:36:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Oct 2020 19:25:25

US3552191

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:36:39

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:17:32
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
DataPoint inactivated with code reason code Data not required.	(b) (4)	
Reviewed for Safety.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:42:43
	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 12:43:07
User entered	System	12 Oct 2020 12:43:02
'USA-US089-2020-mRNA-1273-P301000009'		
User entered 'New'	(b) (4), (b) (6)	12 Oct 2020 12:43:02

US3552191

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:36:39

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:17:30
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 15:44:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	14 Oct 2020 15:44:37
Data point term sent to Coder	System	14 Oct 2020 15:43:48
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
Data point term sent to Coder	(b) (4)	14 Oct 2020 15:42:44
DataPoint inactivated with code reason code Data not required.	System	14 Oct 2020 15:42:44
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\23.0.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:42:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	12 Oct 2020 18:42:29
Data point term sent to Coder	Coder Import (b) (4)	12 Oct 2020 18:42:29
Coding entries removed.	(b) (4)	12 Oct 2020 18:41:37
	System	12 Oct 2020 18:41:34
	Joan Siegner (b) (4)	12 Oct 2020 18:41:34
User entered 'shortness of breath on exertion' reason for change: Data Entry Error	(b) (4)	12 Oct 2020 18:41:34
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\23.0.	Joan Siegner (b) (4)	12 Oct 2020 05:08:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	12 Oct 2020 05:08:30
Data point term sent to Coder	(b) (4)	12 Oct 2020 05:08:30
User entered 'Rule out Congestive Heart Failure'	System	11 Oct 2020 17:11:31
	(b) (4), (b) (6)	11 Oct 2020 17:11:00

US3552191

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:36:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:26:12
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Cassandra Zehenny (b) (4)	14 Oct 2020 15:42:43
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Oct 2020 17:11:00

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:36:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:26:13
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Cassandra Zehenny (b) (4)	14 Oct 2020 15:42:43
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	11 Oct 2020 17:11:00

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:26:21
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Cassandra Zehenny (b) (4)	14 Oct 2020 15:42:43
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	11 Oct 2020 17:11:00

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Folder: Adverse Events

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:30:36
DataPoint Un-verified.	Heather Douds (b) (4)	28 Oct 2020 17:28:14
User entered '30 Sep 2020' reason for change: Data Entry Error	Heather Douds (b) (4)	28 Oct 2020 17:28:14
User closed query 'Since subject was hospitalized for one day to rule out heart failure , please consider updating SAE dates to hospitalization dates 09Oct-10Oct. Per Clinical summary, discharge diagnosis is Dyspnea on exertion - please consider updating SAE term. And Shortness of breath on exertion please consider capturing as an AE. ' (Site from CRA).	(b) (4), (b) (6)	18 Oct 2020 01:25:12
Query 'Since subject was hospitalized for one day to rule out heart failure , please consider updating SAE dates to hospitalization dates 09Oct-10Oct. Per Clinical summary, discharge diagnosis is Dyspnea on exertion - please consider updating SAE term. And Shortness of breath on exertion please consider capturing as an AE. ' answered with 'data is accurate' (Site from CRA).	Joan Siegner (b) (4)	15 Oct 2020 15:24:31
User opened query 'Since subject was hospitalized for one day to rule out heart failure , please consider updating SAE dates to hospitalization dates 09Oct-10Oct. Per Clinical summary, discharge diagnosis is Dyspnea on exertion - please consider updating SAE term. And Shortness of breath on exertion please consider capturing as an AE. ' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 15:03:18
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:26:15
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:42:43
User entered '3 Oct 2020' reason for change: Data Entry Error	Joan Siegner (b) (4)	12 Oct 2020 18:41:34
User entered '9 Oct 2020'	(b) (4), (b) (6)	11 Oct 2020 17:11:00

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:36:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:26:19
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Cassandra Zehenny (b) (4)	14 Oct 2020 15:42:43
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 17:11:00

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:36:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:42:43
User entered empty.	System	11 Oct 2020 17:11:00

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:36:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:59:59
DataPoint Un-verified.	Heather Douds (b) (4)	24 Nov 2020 14:56:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Heather Douds (b) (4)	24 Nov 2020 14:56:54
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:13:31
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	20 Nov 2020 17:04:45
DataPoint Un-verified.	Heather Douds (b) (4)	20 Nov 2020 17:04:45
User entered 'No (N)' reason for change: New Information	Heather Douds (b) (4)	20 Nov 2020 17:04:45
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	20 Nov 2020 17:04:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:13:47
DataPoint Un-verified.	Joan Siegner (b) (4)	11 Nov 2020 17:28:11
User entered 'Yes (Y)' reason for change: New Information	Joan Siegner (b) (4)	11 Nov 2020 17:28:11
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:26:17
User entered 'No (N)' reason for change: New Information	Cassandra Zehenny (b) (4)	14 Oct 2020 16:03:03
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:42:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Oct 2020 17:11:00

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:00:02
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	24 Nov 2020 14:57:10
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	24 Nov 2020 14:57:10
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	24 Nov 2020 14:56:54
DataPoint Un-verified.	Heather Douds (b) (4)	24 Nov 2020 14:56:54
User entered empty; reason for change Data Entry Error	Heather Douds (b) (4)	24 Nov 2020 14:56:54
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 02:55:17
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:13:29
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'recovered' (Site from Safety).	Heather Douds (b) (4)	20 Nov 2020 17:04:54
DataPoint Un-verified.	Heather Douds (b) (4)	20 Nov 2020 17:04:27
User entered '11 Nov 2020' reason for change: New Information	Heather Douds (b) (4)	20 Nov 2020 17:04:27
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 23:23:59
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:13:48
DataPoint Un-verified.	Joan Siegner (b) (4)	11 Nov 2020 17:28:11
User entered empty; reason for change New Information	Joan Siegner (b) (4)	11 Nov 2020 17:28:11

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:17:26
User entered '14 Oct 2020' reason for change: New Information	Cassandra Zehenny (b) (4)	14 Oct 2020 16:03:03
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:42:43
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	11 Oct 2020 17:11:00

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Form: Adverse Events (8)

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End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:26:23
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Cassandra Zehenny (b) (4)	14 Oct 2020 15:42:43
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 17:11:00

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:36:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:42:43
User entered empty.	System	11 Oct 2020 17:11:00

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:36:39

Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:58:24
User closed query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 17:23:11
Query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' answered with 'updated' (Site from Safety).	Heather Douds (b) (4)	22 Oct 2020 16:14:15
DataPoint Un-verified.	(b) (4)	22 Oct 2020 16:14:10
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Heather Douds (b) (4)	22 Oct 2020 16:14:10
User opened query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 17:46:11
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:17:23
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
DataPoint inactivated with code reason code Data not required.	(b) (4)	14 Oct 2020 15:42:43
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	11 Oct 2020 17:11:00

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Folder: Adverse Events

Form: Adverse Events (8)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'Hospitalization date is 09Oct, event was reported as an SAE on 11Oct. Please provide the date of awareness. ' (Site from CRA).	(b) (4), (b) (6)	18 Oct 2020 01:25:27
Query 'Hospitalization date is 09Oct, event was reported as an SAE on 11Oct. Please provide the date of awareness. ' answered with 'Site awareness 10/10. Reported on 10/11.' (Site from CRA).	Joan Siegner (b) (4)	15 Oct 2020 15:25:12
User opened query 'Hospitalization date is 09Oct, event was reported as an SAE on 11Oct. Please provide the date of awareness. ' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 15:04:30
Query 'Event is reported as SAE on 11Oct2020. Start date is 06Oct2020. Please indicate the date of awareness. If SAE is not reported within 24 hrs of awareness date, this should be captured as PD.' canceled (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 15:03:44
User opened query 'Event is reported as SAE on 11Oct2020. Start date is 06Oct2020. Please indicate the date of awareness. If SAE is not reported within 24 hrs of awareness date, this should be captured as PD.' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 14:40:11
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:17:21
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:42:43
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	11 Oct 2020 17:12:11
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	11 Oct 2020 17:11:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Oct 2020 17:11:00

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:36:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:26:25
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Cassandra Zehenny (b) (4)	14 Oct 2020 15:42:43
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	11 Oct 2020 17:11:00

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:36:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:26:26
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Cassandra Zehenny (b) (4)	14 Oct 2020 15:42:43
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	11 Oct 2020 17:11:00

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:36:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:26:28
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:42:43
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	11 Oct 2020 17:12:11
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	11 Oct 2020 17:12:11
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Oct 2020 17:12:11
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	11 Oct 2020 17:11:00
User entered '0'	(b) (4), (b) (6)	11 Oct 2020 17:11:00

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:36:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:16:54
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Cassandra Zehenny (b) (4)	14 Oct 2020 15:42:43
	(b) (4)	
User entered '09 Oct 2020'	(b) (4), (b) (6)	11 Oct 2020 17:11:00

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Folder: Adverse Events

Form: Adverse Events (8)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:16:56
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Cassandra Zehenny (b) (4)	14 Oct 2020 15:42:43
	(b) (4)	
User entered '10 Oct 2020'	(b) (4), (b) (6)	11 Oct 2020 17:11:00

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:16:57
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Cassandra Zehenny (b) (4)	14 Oct 2020 15:42:43
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	11 Oct 2020 17:11:00

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:26:29
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Cassandra Zehenny (b) (4)	14 Oct 2020 15:42:43
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 17:11:00

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Folder: Adverse Events

Form: Adverse Events (8)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:26:31
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Cassandra Zehenny (b) (4)	14 Oct 2020 15:42:43
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	11 Oct 2020 17:11:00

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Folder: Adverse Events

Form: Adverse Events (8)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:26:32
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Cassandra Zehenny (b) (4)	14 Oct 2020 15:42:43
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	11 Oct 2020 17:11:00

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Folder: Adverse Events

Form: Adverse Events (8)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:26:34
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Cassandra Zehenny (b) (4)	14 Oct 2020 15:42:43
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	11 Oct 2020 17:11:00

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the investigator's rationale for assessing this event as related to study drug.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 13:05:01
Query 'PV Query: Please provide the investigator's rationale for assessing this event as related to study drug.' answered with 'Per Dr. Frey: Subject does not have any known history of cardiac disease. Subject's fatigue started day after second vaccination and then shortness of breath/dyspnea on exertion, bilateral ankle edema, cough, muscle aches, tachycardia, and sore throat all started within 16 days of second vaccination. There is no other known etiology for this. She does have multiple underlying comorbidities, including diabetes. LVEF and troponin were unremarkable from hospital admission. A low hemoglobin was noted and we await a repeat test.' (Site from Safety).	Cassandra Zehenny (b) (4)	23 Oct 2020 16:01:46
User opened query 'PV Query: Please provide the investigator's rationale for assessing this event as related to study drug.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 17:45:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:26:35
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:42:43
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)	13 Oct 2020 13:30:07
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'done' (Site from Safety).	Joan Siegner (b) (4)	12 Oct 2020 18:41:46
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 18:41:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Oct 2020 18:41:34
User entered 'Related (RELATED)' reason for change: Data Entry Error	Joan Siegner (b) (4)	12 Oct 2020 18:41:34
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)	12 Oct 2020 12:42:40

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Oct 2020 17:11:00
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 17:11:00

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:26:39
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:42:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Oct 2020 18:41:34
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	System	12 Oct 2020 18:41:34
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Joan Siegner (b) (4)	12 Oct 2020 18:41:34
User opened query 'Data is required. Please complete.' (Site from System).		
User entered empty.	System	11 Oct 2020 17:11:00
	(b) (4), (b) (6)	11 Oct 2020 17:11:00

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None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:26:41
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Cassandra Zehenny (b) (4)	14 Oct 2020 15:42:43
	(b) (4)	
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	12 Oct 2020 17:02:06
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	11 Oct 2020 17:11:00
User entered '0'	(b) (4), (b) (6)	11 Oct 2020 17:11:00

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Folder: Adverse Events

Form: Adverse Events (8)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:17:06
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
DataPoint inactivated with code reason code Data not required.	(b) (4)	
User entered '1' reason for change: New Information	Cassandra Zehenny (b) (4)	14 Oct 2020 15:42:43
	(b) (4)	
User entered '0'	(b) (4)	12 Oct 2020 17:02:06
	(b) (4), (b) (6)	11 Oct 2020 17:11:00

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Form: Adverse Events (8)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:58:32
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Cassandra Zehenny (b) (4)	14 Oct 2020 15:42:43
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	11 Oct 2020 17:11:00

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:36:39

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:00:08
DataPoint Un-verified.	Heather Douds (b) (4)	24 Nov 2020 14:57:10
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: New Information	Heather Douds (b) (4)	24 Nov 2020 14:57:10
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 02:55:24
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:13:38
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'recovered' (Site from Safety).	Heather Douds (b) (4)	20 Nov 2020 17:05:00
DataPoint Un-verified.	Heather Douds (b) (4)	20 Nov 2020 17:04:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Heather Douds (b) (4)	20 Nov 2020 17:04:27
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 23:24:18
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:13:53
DataPoint Un-verified.	Joan Siegner (b) (4)	11 Nov 2020 17:28:11
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: New Information	Joan Siegner (b) (4)	11 Nov 2020 17:28:11
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:17:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Cassandra Zehenny (b) (4)	14 Oct 2020 16:03:03

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:36:39

[Outcome](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:42:43
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 17:02:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Oct 2020 17:02:06
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: New Information	Cassandra Zehenny (b) (4)	12 Oct 2020 17:02:06
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Oct 2020 17:11:00
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 17:11:00

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:36:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:58:28
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Cassandra Zehenny (b) (4)	14 Oct 2020 15:42:43
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 17:11:00

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:36:39

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:42:17
DataPoint Un-verified.	Heather Douds (b) (4)	23 Nov 2020 19:57:58
User entered 'SUBJECT NOTIFIED SITE 07OCT2020 OF SHORTNESS OF BREATH ON EXERTION, FATIGUE AND SWOLLEN ANKLES. SITE SENT HOME HEALTH NURSES TO HER HOME ON 08OCT2020 TO DO ILLNESS VISIT AND ADVISED HER TO NOTIFY HER PCP OF SYMPTOMS. SUBJECT SAW PCP ON 09OCT2020 AND WAS SENT TO ER FOR CARDIAC EVALUATION. WAS ADMITTED OVERNIGHT TO HOSPITAL AND TREATED WITH IVP LASIX AND DIURESED. HAD LAB WORK, ECG AND CT OF CHEST. DISCHARGED THE NEXT DAY AND HAD ECHOCARDIOGRAM THE AM OF 12OCT2020. HOSPITAL MEDICAL RECORDS RECEIVED AND SENT TO SPONSOR. PER CARDIOLOGIST'S OFFICE, ECHO NEGATIVE. X RAY "WITHOUT SIGNIFICANT OR ACUTE FINDINGS," CHEST CT "NO EVIDENCE OF PE," ECG "SINUS TACHYCARDIA, NO EVIDENCE OF INJURY PATTERN."' reason for change: New Information	Heather Douds (b) (4)	23 Nov 2020 19:57:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:13:36
DataPoint Un-verified.	Heather Douds (b) (4)	20 Nov 2020 17:04:27

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:36:39

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT NOTIFIED SITE 07OCT2020 OF SHORTNESS OF BREATH ON EXERTION, FATIGUE AND SWOLLEN ANKLES. SITE SENT HOME HEALTH NURSES TO HER HOME ON 08OCT2020 TO DO ILLNESS VISIT AND ADVISED HER TO NOTIFY HER PCP OF SYMPTOMS. SUBJECT SAW PCP ON 09OCT2020 AND WAS SENT TO ER FOR CARDIAC EVALUATION. WAS ADMITTED OVERNIGHT TO HOSPITAL AND TREATED WITH IVP LASIX AND DIURESED. HAD LAB WORK, ECG AND CT OF CHEST. DISCHARGED THE NEXT DAY AND HAD ECHOCARDIOGRAM THE AM OF 12OCT2020. HOSPITAL MEDICAL RECORDS RECEIVED AND SENT TO SPONSOR. PER CARDIOLOGIST'S OFFICE, ECHO NEGATIVE. X RAY "WITHOUT SIGNIFICANT OR ACUTE FINDINGS," CHEST CT "NO EVIDENCE OF PE," ECG "SINUS TACHYCARDIA, NO EVIDENCE OF INJURY PATTERN." As of 11/18 phone call, subject reports that it has resolved.' reason for change: New Information	Heather Douds (b) (4) (b) (4)	20 Nov 2020 17:04:27
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:58:30
User closed query 'PV Query: Please confirm if there is another pending COVID-19 test and the result.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 17:23:17
Query 'PV Query: Please confirm if there is another pending COVID-19 test and the result.' answered with 'No additional tests pending' (Site from Safety).	Heather Douds (b) (4) (b) (4)	22 Oct 2020 16:09:28
User opened query 'PV Query: Please confirm if there is another pending COVID-19 test and the result.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 17:45:56
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	15 Oct 2020 16:06:57

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:36:39

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT NOTIFIED SITE 07OCT2020 OF SHORTNESS OF BREATH ON EXERTION, FATIGUE AND SWOLLEN ANKLES. SITE SENT HOME HEALTH NURSES TO HER HOME ON 08OCT2020 TO DO ILLNESS VISIT AND ADVISED HER TO NOTIFY HER PCP OF SYMPTOMS. SUBJECT SAW PCP ON 09OCT2020 AND WAS SENT TO ER FOR CARDIAC EVALUATION. WAS ADMITTED OVERNIGHT TO HOSPITAL AND TREATED WITH IVP LASIX AND DIURESED. HAD LAB WORK, ECG AND CT OF CHEST. DISCHARGED THE NEXT DAY AND HAD ECHOCARDIOGRAM THE AM OF 12OCT2020. HOSPITAL MEDICAL RECORDS RECEIVED AND SENT TO SPONSOR. PER CARDIOLOGIST'S OFFICE, ECHO NEGATIVE. X RAY "WITHOUT SIGNIFICANT OR ACUTE FINDINGS," CHEST CT "NO EVIDENCE OF PE," ECG "SINUS TACHYCARDIA, NO EVIDENCE OF INJURY PATTERN"' reason for change: Data Entry Error	Heather Douds (b) (4)	15 Oct 2020 16:06:57
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:17:12
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:42:43
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	12 Oct 2020 18:41:34
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	12 Oct 2020 18:41:34

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:36:39

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject reported shortness of breath on Joan Siegner exertion with fatigue and swollen ankles on 07OCT2020. Site sent home health nurses to perform illness visit on 08OCT2020 and advised subject to contact her PCP re: these continuing symptoms. Subject was evaluated by PCP on 09OCT2020 and was sent to ER for cardiac work-up. Admitted to the hospital and had labs, CT chest, ECG and cardiac consult performed. Treated with IVP lasix and experienced diuresis. Discharged the next day. To have echocardiogram done in AM of 12OCT2020 and to follow up with cardiologist. Medical records for hospitalization received and scanned to sponsor.' reason for change: Data Entry Error	(b) (4)	12 Oct 2020 18:41:34
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	11 Oct 2020 17:11:00
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 17:11:00

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:36:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:42:43
User entered '1'	System	11 Oct 2020 17:11:00

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:36:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:42:43
User entered '1'	System	11 Oct 2020 17:11:00

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:36:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:43:29
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:42:43
User entered '0'	System	11 Oct 2020 17:11:00

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Folder: Adverse Events

Form: Adverse Events (9)

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[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:05
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 15:30:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	14 Oct 2020 15:30:27
User entered 'Anemia'	(b) (4)	
	System	14 Oct 2020 15:29:10
	Mikayla Frye (b) (4)	14 Oct 2020 15:28:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:36:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:06
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 15:28:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 15:28:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Mikayla Frye (b) (4)	14 Oct 2020 15:28:54
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 15:28:47
User entered empty.	Mikayla Frye (b) (4)	14 Oct 2020 15:28:47

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:36:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:08
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:28:47

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:36:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:10
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:28:47

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:12
User entered '09 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 15:29:11
User entered '9 Oct 2020'	Mikayla Frye (b) (4)	14 Oct 2020 15:28:47

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:36:39

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:28:47

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:36:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 15:28:47

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:36:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Stanley Dublin (b) (4)	19 Nov 2020 13:16:16
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Stanley Dublin (b) (4)	19 Nov 2020 13:16:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Yes (Y)'	Mikayla Frye (b) (4)	14 Oct 2020 15:28:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:36:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	Stanley Dublin (b) (4)	19 Nov 2020 13:16:16
	(b) (4)	
User entered '20 Oct 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	19 Nov 2020 13:16:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4)	14 Oct 2020 15:28:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:36:39

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:28:47

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:36:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 15:28:47

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:36:39

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:28:47

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:36:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:28:47

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:36:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:28:47

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:36:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:28:47

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:36:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:28:47

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:36:39

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:28:47

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Folder: Adverse Events

Form: Adverse Events (9)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:28:47

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Folder: Adverse Events

Form: Adverse Events (9)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:28:47

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Folder: Adverse Events

Form: Adverse Events (9)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:28:47

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:36:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:28:47

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Folder: Adverse Events

Form: Adverse Events (9)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:28:47

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Folder: Adverse Events

Form: Adverse Events (9)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:28:47

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Folder: Adverse Events

Form: Adverse Events (9)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Not Related (NOT RELATED)'	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:28:47

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Folder: Adverse Events

Form: Adverse Events (9)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Not Related (NOT RELATED)'	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:28:47

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Folder: Adverse Events

Form: Adverse Events (9)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Stanley Dublin (b) (4)	23 Nov 2020 17:41:47
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Stanley Dublin (b) (4)	23 Nov 2020 17:41:47
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'None (NONE)'	Mikayla Frye (b) (4)	14 Oct 2020 15:28:47
	(b) (4)	

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '1'	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:28:47

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:36:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:28:47

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Folder: Adverse Events

Form: Adverse Events (9)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:28:47

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:36:39

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Stanley Dublin (b) (4)	19 Nov 2020 13:16:16
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Stanley Dublin (b) (4)	19 Nov 2020 13:16:16
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mikayla Frye (b) (4)	14 Oct 2020 15:28:47
	(b) (4)	

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:28:47

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:28:47

US3552191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:36:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Oct 2020 15:28:47

US3552191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:36:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 15:28:54

US3552191

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:20
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Sinus tachycardia, LLT: Sinus tachycardia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 12:28:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 12:28:06
User closed query 'Per DM CLR: Please specify the type (e.g., Sinus Tachycardia, Ventricular Tachycardia, etc) of TACHYCARDIA. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.	(b) (4), (b) (6)	05 Nov 2020 04:17:59
' (Site from DM).		
Data point term sent to Coder	System	02 Nov 2020 20:44:00
Query 'Per DM CLR: Please specify the type (e.g., Sinus Tachycardia, Ventricular Tachycardia, etc) of TACHYCARDIA. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.	Cassandra Zehenny (b) (4) (b) (4)	02 Nov 2020 20:43:42
' answered with 'updated' (Site from DM).		
Coding entries removed.	Cassandra Zehenny (b) (4) (b) (4)	02 Nov 2020 20:43:38
User entered 'SINUS TACHYCARDIA' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	02 Nov 2020 20:43:38
User opened query 'Per DM CLR: Please specify the type (e.g., Sinus Tachycardia, Ventricular Tachycardia, etc) of TACHYCARDIA. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.	(b) (4), (b) (6)	02 Nov 2020 11:45:03
' (Site from DM).		
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Tachycardia, LLT: Tachycardia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:10:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:10:29
Data point term sent to Coder	System	15 Oct 2020 16:09:28

US3552191

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Tachycardia'	Heather Douds (b) (4) (b) (4)	15 Oct 2020 16:09:20

US3552191

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:22
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	15 Oct 2020 16:09:20

US3552191

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:23
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	15 Oct 2020 16:09:20

US3552191

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:24
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	15 Oct 2020 16:09:20

US3552191

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:26
User entered '09 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 15:29:22
User entered '9 Oct 2020'	Heather Douds (b) (4)	15 Oct 2020 16:09:20

US3552191

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Heather Douds (b) (4) (b) (4)	15 Oct 2020 16:09:20

US3552191

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 16:09:20

US3552191

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:18:47
DataPoint Un-verified.	Stanley Doublin (b) (4)	19 Nov 2020 13:17:14
User entered 'No (N)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	19 Nov 2020 13:17:14
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Yes (Y)'	Heather Douds (b) (4)	15 Oct 2020 16:09:20

US3552191

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:18:53
DataPoint Un-verified.	Stanley Doublin (b) (4)	19 Nov 2020 13:17:14
User entered '09 Nov 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4)	19 Nov 2020 13:17:14
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Heather Douds (b) (4)	15 Oct 2020 16:09:20

US3552191

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Heather Douds (b) (4) (b) (4)	15 Oct 2020 16:09:20

US3552191

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 16:09:20

US3552191

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Grade 1/Mild (Grade 1/Mild)'	Heather Douds (b) (4) (b) (4)	15 Oct 2020 16:09:20

US3552191

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	15 Oct 2020 16:09:20

US3552191

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Heather Douds (b) (4) (b) (4)	15 Oct 2020 16:09:20

US3552191

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Heather Douds (b) (4) (b) (4)	15 Oct 2020 16:09:20

US3552191

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Heather Douds (b) (4) (b) (4)	15 Oct 2020 16:09:20

US3552191

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Heather Douds (b) (4) (b) (4)	15 Oct 2020 16:09:20

US3552191

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Heather Douds (b) (4) (b) (4)	15 Oct 2020 16:09:20

US3552191

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Heather Douds (b) (4) (b) (4)	15 Oct 2020 16:09:20

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Heather Douds (b) (4) (b) (4)	15 Oct 2020 16:09:20

US3552191

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Heather Douds (b) (4) (b) (4)	15 Oct 2020 16:09:20

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Heather Douds (b) (4) (b) (4)	15 Oct 2020 16:09:20

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Heather Douds (b) (4) (b) (4)	15 Oct 2020 16:09:20

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 20:10:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 20:10:11
User entered 'Related (RELATED)' reason for change: Data Entry Error	Mikayla Frye (b) (4)	15 Oct 2020 20:10:11
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 16:09:20
User entered empty.	Heather Douds (b) (4)	15 Oct 2020 16:09:20

US3552191

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 20:10:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 20:10:11
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Mikayla Frye (b) (4)	15 Oct 2020 20:10:11
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 16:09:20
User entered empty.	Heather Douds (b) (4)	15 Oct 2020 16:09:20

US3552191

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Stanley Dublin (b) (4)	23 Nov 2020 17:41:58
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Stanley Dublin (b) (4)	23 Nov 2020 17:41:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 20:10:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 20:10:11
User entered 'None (NONE)' reason for change: Data Entry Error	Mikayla Frye (b) (4)	15 Oct 2020 20:10:11
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 16:09:20
User entered empty.	Heather Douds (b) (4)	15 Oct 2020 16:09:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	15 Oct 2020 20:10:11
User entered '1' reason for change: Data Entry Error	Mikayla Frye (b) (4)	15 Oct 2020 20:10:11
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	15 Oct 2020 16:09:20
User entered '0'	Heather Douds (b) (4) (b) (4)	15 Oct 2020 16:09:20

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Heather Douds (b) (4) (b) (4)	15 Oct 2020 16:09:20

US3552191

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Heather Douds (b) (4) (b) (4)	15 Oct 2020 16:09:20

US3552191

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Stanley Dublin (b) (4)	19 Nov 2020 13:17:14
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Stanley Dublin (b) (4)	19 Nov 2020 13:17:14
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 20:10:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 20:10:11
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Mikayla Frye (b) (4)	15 Oct 2020 20:10:11
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 16:09:20
User entered empty.	Heather Douds (b) (4)	15 Oct 2020 16:09:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Heather Douds (b) (4) (b) (4)	15 Oct 2020 16:09:20

US3552191

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Heather Douds (b) (4) (b) (4)	15 Oct 2020 16:09:20

US3552191

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Oct 2020 16:09:20

US3552191

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:36:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 16:09:20

US3552191

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:17:02
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle weakness conditions, PT: Muscular weakness, LLT: Muscle weakness - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 20:50:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 20:50:36
Data point term sent to Coder	System	20 Oct 2020 20:49:31
User entered 'Muscle Weakness'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:48:53

US3552191

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:17:04
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53

US3552191

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:17:06
User entered 'No (N)'	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53

US3552191

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:17:07
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:48:53

US3552191

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:35
Query 'Per source, muscle weakness start date 19Oct. Please reconcile, ' canceled (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 18:14:34
User opened query 'Per source, muscle weakness start date 19Oct. Please reconcile, ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 16:17:46
User entered '09 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 15:29:32
User entered '9 Oct 2020'	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53

US3552191

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53
	(b) (4)	

US3552191

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 20:48:53

US3552191

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53
	(b) (4)	

US3552191

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 20:48:53

US3552191

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53

US3552191

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'No (N)'	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53

US3552191

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53

US3552191

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53

US3552191

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53

US3552191

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53

US3552191

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53

US3552191

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:48:53

US3552191

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53

US3552191

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53

US3552191

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Related (RELATED)'	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53

US3552191

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:48:53

US3552191

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Not Applicable (NOT APPLICABLE)'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:48:53

US3552191

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '1'	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53

US3552191

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53

US3552191

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53

US3552191

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:48:53

US3552191

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53
	(b) (4)	

US3552191

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53

US3552191

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Oct 2020 20:48:53

US3552191

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:36:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 20:48:53

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:16:31
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hyperfunction disorders, PT: Hyperthyroidism, LLT: Hyperthyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 17:27:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	27 Oct 2020 17:27:04
Data point term sent to Coder	System	27 Oct 2020 17:21:06
User entered 'hyperthyroidism'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:16:33
User entered 'Yes (Y)'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:16:35
User entered 'No (N)'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:16:37
User entered 'No (N)'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:16:49
User entered '26 Oct 2020'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Yes (Y)'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Grade 3/Severe (Grade 3/Severe)'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'No (N)'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Not Related (NOT RELATED)'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Not Related (NOT RELATED)'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Not Applicable (NOT APPLICABLE)'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '1'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 17:20:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 17:20:53
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Joan Siegner (b) (4)	27 Oct 2020 17:20:53
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 17:20:45
User entered empty.	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:36:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Pruritus NEC, PT: Pruritus, LLT: Itching - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 13:39:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 13:39:03
Data point term sent to Coder	System	19 Nov 2020 13:38:21
User entered 'itching'	Stanley Doublin (b) (4)	19 Nov 2020 13:37:33
	(b) (4)	

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
User entered '09 Nov 2020'	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

[If not Ongoing, end date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Stanley Dublin (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

[None](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:36:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 13:37:33

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:36:39

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:15:03
User closed query 'Per ETRTR: According to SAE "Shortness of Breath" and SAE "Bilateral Ankle Edema", medication was dosed for both SAEs. Please confirm details on medication dosed, thanks' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 02:03:24
Query 'Per ETRTR: According to SAE "Shortness of Breath" and SAE "Bilateral Ankle Edema", medication was dosed for both SAEs. Please confirm details on medication dosed, thanks' answered with 'Noted, thank you.' (Site from CRA).	Cassandra Zehenny (b) (4)	14 Oct 2020 15:26:25
User opened query 'Per ETRTR: According to SAE "Shortness of Breath" and SAE "Bilateral Ankle Edema", medication was dosed for both SAEs. Please confirm details on medication dosed, thanks' (Site from CRA).	(b) (4), (b) (6)	13 Oct 2020 22:46:16
Query 'Per ETRTR: According to SAE "Bilateral Ankle Edema", medication was dosed for SAE. Please confirm details on medication dosed, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	13 Oct 2020 22:45:35
User opened query 'Per ETRTR: According to SAE "Bilateral Ankle Edema", medication was dosed for SAE. Please confirm details on medication dosed, thanks.' (Site from CRA).	(b) (4), (b) (6)	13 Oct 2020 22:39:20
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	27 Aug 2020 15:07:17

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User closed query 'Please add EKG, chest Xray CT to the Concomitant procedures eCRF .' (Site from CRA).	(b) (4), (b) (6)	24 Oct 2020 23:23:20
Query 'Please add EKG, chest Xray CT to the Concomitant procedures eCRF .' answered with 'see narrative' (Site from CRA).	Heather Douds (b) (4) (b) (4)	15 Oct 2020 15:33:22
User opened query 'Please add EKG, chest Xray CT to the Concomitant procedures eCRF .' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 14:12:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:25:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:25:36
Data point term sent to Coder	System	27 Aug 2020 15:13:04
User entered 'METFORMIN' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:12:59
User entered 'methormin'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:12:40

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:12:40

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'type 2 diabetes mellitus'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:12:40

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '500'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:12:40

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:12:40

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:12:40

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'twice daily (BID)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:12:40

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:12:40

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:12:40

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:12:40

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'un Jun 2018'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:12:40

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:12:40

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:12:40

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:12:40

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:12:40

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	27 Aug 2020 15:12:40

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:12:40

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 15:12:40

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION, ATC: LOW-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS, PRODUCT: HYDROCHLOROTHIAZIDE;TRIAMTERENE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:42:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:42:38
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	28 Oct 2020 17:34:17 28 Oct 2020 17:34:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION, ATC: LOW-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS, PRODUCT: HYDROCHLOROTHIAZIDE;TRIAMTERENE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 10:42:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 10:42:49
Data point term sent to Coder	System	27 Aug 2020 15:14:05
User entered 'HCTZ / triamterene'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:14:02

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:14:02

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'meniere's disease'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:14:02

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '25 / 37.5'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:14:02

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:14:02

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:14:02

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:14:02

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:14:02

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:14:02

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:14:02

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'un UNK 2015'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:14:02

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:14:02

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:14:02

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:14:02

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:14:02

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:14:02

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:14:02

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 15:14:02

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:39

[Name of Medication](#)

Audit	User	Time (GMT)
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) (b) (4)	29 Oct 2020 19:42:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:42:37
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	28 Oct 2020 17:34:19 28 Oct 2020 17:34:15
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) (b) (4)	27 Aug 2020 19:25:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:25:48
Data point term sent to Coder User entered 'atorvastatin'	System Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:16:07 27 Aug 2020 15:15:31

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:15:31

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'hypercholesterolemia'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:15:31

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '40'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:15:31

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:15:31

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:15:31

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:15:31

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:15:31

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:15:31

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:15:31

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'un UNK 2010'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:15:31

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:15:31

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:15:31

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:15:31

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:15:31

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:15:31

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:15:31

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 15:15:31

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VENLAFAXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:42:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:42:36
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	28 Oct 2020 17:34:21 28 Oct 2020 17:34:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VENLAFAXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:26:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:26:19
Data point term sent to Coder	System	27 Aug 2020 15:18:17
User entered 'VENLAFAXINE' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:17:26
Data point term sent to Coder	System	27 Aug 2020 15:17:15
User entered 'vanlafazine'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:17:08

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:17:08

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'mild depression'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:17:08

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '75'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:17:08

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:17:08

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:17:08

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:17:08

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:17:08

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:17:08

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:17:08

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'un UNK 1990'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:17:08

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:17:08

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:17:08

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:17:08

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:17:08

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:17:08

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:17:08

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 15:17:08

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Oct 2020 19:42:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Oct 2020 19:42:36
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	28 Oct 2020 17:34:18 28 Oct 2020 17:34:15
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Oct 2020 16:31:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Oct 2020 16:31:15
Data point term sent to Coder Coding entries removed.	System Cassandra Zehenny (b) (4)	05 Oct 2020 14:55:39 05 Oct 2020 14:54:44
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Aug 2020 19:26:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Aug 2020 19:26:18
Data point term sent to Coder User entered 'vitamin b12'	System Stanley Dublin (b) (4)	27 Aug 2020 15:19:18 27 Aug 2020 15:18:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:18:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'REPLACEMENT for or preventative OF METFORMIN DEPLETION' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	05 Oct 2020 14:54:44
User entered 'replacement for orpersentive of metformin depletion'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:18:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '1000'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:18:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:18:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:18:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'once daily (QD)' reason for change:	Cassandra Zehenny (b) (4)	05 Oct 2020 14:54:44
Data Entry Error	(b) (4)	
User entered 'once (ONCE)'	Stanley Doublin (b) (4)	27 Aug 2020 15:18:54
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:18:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:18:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:18:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'un Jun 2018'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:18:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:18:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User closed query 'Per DM CLR: Frequency = Once, however the Con Med is still ongoing. Please verify and update either the frequency (e.g., Daily) or the start/end dates on the Con Med eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 09:23:07
Query 'Per DM CLR: Frequency = Once, however the Con Med is still ongoing. Please verify and update either the frequency (e.g., Daily) or the start/end dates on the Con Med eCRF as appropriate. Otherwise, provide clarification. ' answered with 'Correct' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	05 Oct 2020 14:54:51
User opened query 'Per DM CLR: Frequency = Once, however the Con Med is still ongoing. Please verify and update either the frequency (e.g., Daily) or the start/end dates on the Con Med eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 07:19:19
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:18:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:18:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:18:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 14:54:44
User entered empty.	System	27 Aug 2020 15:18:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 14:54:44
User entered empty.	System	27 Aug 2020 15:18:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 14:54:44
User entered empty.	System	27 Aug 2020 15:18:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:42:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:42:36
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	28 Oct 2020 17:34:24 28 Oct 2020 17:34:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:26:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:26:18
Data point term sent to Coder User entered 'gabapentin'	System Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:20:19 27 Aug 2020 15:19:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:19:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'osteoarthritis'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:19:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '300'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:19:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:19:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:19:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'as needed (PRN)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:19:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:19:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:19:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:19:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'un UNK 2016'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:19:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:19:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:19:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:19:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:19:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 15:19:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 15:19:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 15:19:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:42:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:42:36
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	28 Oct 2020 17:34:23 28 Oct 2020 17:34:15
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: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:26:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:26:24
Data point term sent to Coder	System	27 Aug 2020 15:21:19
User entered 'vitamin d3'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:20:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:20:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'vitamin d deficiency'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:20:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '50'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:20:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'ug (ug)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:20:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:20:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:20:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:20:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:20:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:20:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'un UNK 2012'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:20:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:20:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:20:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:20:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:20:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:20:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:20:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 15:20:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:42:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:42:36
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	28 Oct 2020 17:34:26 28 Oct 2020 17:34:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:15:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:15:53

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:39

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, COMBINATIONS, ATC: MULTIVITAMINS WITH MINERALS, PRODUCT: ASCORBIC ACID;BIOTIN;CALCIUM;CALCIUM PHOSPHATE DIBASIC;CHROMIC CHLORIDE;CUPRIC OXIDE;CYANOCOBALAMIN;FERROUS FUMARATE;FOLIC ACID;MAGNESIUM OXIDE;MANGANESE SULFATE;NICKEL SULFATE;NICOTINAMIDE;PANTOTHENIC ACID;PHYTOMENADIONE;POTASSIUM CHLORIDE;POTASSIUM IODIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;SODIUM METASILICATE;SODIUM MOLYBDATE;SODIUM SELENATE;THIAMINE MONONITRATE;TOCOPHERYL ACETATE;VITAMIN D NOS;ZINC OXIDE, PRODUCTSYNONYM: CENTRUM SILVER [ASCORBIC ACID;BIOTIN;CALCIUM;CALCIUM PHOSPHATE DIBASIC;CHROMIC CHLORIDE;CUPRIC OXIDE;CYANOCOBALAMIN;FERROUS FUMARATE;FOLIC ACID;MAGNESIUM OXIDE;MANGANESE SULFATE;NICKEL SULFATE;NICOTINAMIDE;PANTOTHENIC ACID;PHYTOMENADIONE;POTASSIUM CHLORIDE;POTASSIUM IODIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;SODIUM METASILICATE;SODIUM MOLYBDATE;SODIUM SELENATE;THIAMINE MONONITRATE;TOCOPHERYL ACETATE;VITAMIN D NOS;ZINC OXIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 17:43:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 17:43:56

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 00:51:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 00:51:39
Data point term sent to Coder	System	27 Aug 2020 16:50:31
User entered 'centrum silver'	Joan Siegner (b) (4) (b) (4) (b) (4)	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Stanley Dublin (b) (4)	11 Nov 2020 16:41:13
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Stanley Dublin (b) (4)	11 Nov 2020 16:41:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Joan Siegner (b) (4)	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'health promotion'	Joan Siegner (b) (4)	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '1'	Joan Siegner (b) (4)	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'tablet (TABLET)'	Joan Siegner (b) (4)	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Joan Siegner (b) (4)	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'once daily (QD)'	Joan Siegner (b) (4)	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Joan Siegner (b) (4)	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Oral (ORAL)'	Joan Siegner (b) (4)	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Joan Siegner (b) (4)	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'un UNK 2014'	Joan Siegner (b) (4)	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '0'	Joan Siegner (b) (4)	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Yes (Y)'	Joan Siegner (b) (4)	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Joan Siegner (b) (4)	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Joan Siegner (b) (4)	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MAGNESIUM CITRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:42:37
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 Oct 2020 19:42:37
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	28 Oct 2020 17:34:23 28 Oct 2020 17:34:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MAGNESIUM CITRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 11:55:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 11:55:44
Data point term sent to Coder User entered 'magnesium citrate'	System Joan Siegner (b) (4)	27 Aug 2020 16:51:36 27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Joan Siegner (b) (4)	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'constipation'	Joan Siegner (b) (4)	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '250'	Joan Siegner (b) (4)	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'mg (mg)'	Joan Siegner (b) (4)	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Joan Siegner (b) (4)	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'once daily (QD)'	Joan Siegner (b) (4)	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Joan Siegner (b) (4)	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Oral (ORAL)'	Joan Siegner (b) (4)	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:39

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Joan Siegner (b) (4)	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'un UNK 2019'	Joan Siegner (b) (4)	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '0'	Joan Siegner (b) (4)	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Yes (Y)'	Joan Siegner (b) (4)	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Joan Siegner (b) (4)	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Joan Siegner (b) (4)	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:42:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:42:37
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	28 Oct 2020 17:34:24 28 Oct 2020 17:34:15
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:39:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:39:02
Data point term sent to Coder User entered 'cetirizine'	System Joan Siegner (b) (4) (b) (4)	27 Aug 2020 16:52:38 27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Joan Siegner (b) (4)	27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'seasonal allergies'	Joan Siegner (b) (4)	27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '10'	Joan Siegner (b) (4)	27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'mg (mg)'	Joan Siegner (b) (4)	27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Joan Siegner (b) (4)	27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'once daily (QD)'	Joan Siegner (b) (4)	27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Joan Siegner (b) (4)	27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Oral (ORAL)'	Joan Siegner (b) (4)	27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Joan Siegner (b) (4)	27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'un UNK 2017'	Joan Siegner (b) (4)	27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '0'	Joan Siegner (b) (4)	27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Yes (Y)'	Joan Siegner (b) (4)	27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Joan Siegner (b) (4)	27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Joan Siegner (b) (4)	27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:42:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:42:41
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	28 Oct 2020 17:34:30 28 Oct 2020 17:34:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 17:01:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 17:01:37
Data point term sent to Coder User entered 'Lasix'	System Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 15:39:36 14 Oct 2020 15:39:33

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Cassandra Zehenny (b) (4)	14 Oct 2020 15:39:33

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Shortness of breath and bilateral lower leg edema'	Cassandra Zehenny (b) (4)	14 Oct 2020 15:39:33

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '20'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 15:39:33

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'mg (mg)'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 15:39:33

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 15:39:33

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'once (ONCE)'	Cassandra Zehenny (b) (4)	14 Oct 2020 15:39:33

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 15:39:33

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Intravenous (INTRAVENOUS)'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 15:39:33

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:39:33
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:28:15
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	09 Nov 2020 15:23:18
User entered '09 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	09 Nov 2020 15:23:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '9 Oct 2020'	Cassandra Zehenny (b) (4)	14 Oct 2020 15:39:33
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '0'	Cassandra Zehenny (b) (4)	14 Oct 2020 15:39:33

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Cassandra Zehenny (b) (4)	14 Oct 2020 15:39:33
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:28:20
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	09 Nov 2020 15:23:18
User entered '09 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	09 Nov 2020 15:23:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '9 Oct 2020'	Cassandra Zehenny (b) (4)	14 Oct 2020 15:39:33
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Cassandra Zehenny (b) (4)	14 Oct 2020 15:39:33

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 15:39:33

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 15:39:33

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 15:39:33

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL, PRODUCTSYNONYM: COREG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:42:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:42:40
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	28 Oct 2020 17:34:28 28 Oct 2020 17:34:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL, PRODUCTSYNONYM: COREG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 16:49:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 16:49:34
Data point term sent to Coder User entered 'coreg'	System Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:48:55 27 Oct 2020 16:48:36
DataPoint activated with code reason code Data required.	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:47:34
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4) (b) (4)	15 Oct 2020 15:27:47

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Mikayla Frye (b) (4)	27 Oct 2020 16:48:36
DataPoint activated with code reason code Data required.	Mikayla Frye (b) (4)	27 Oct 2020 16:47:34
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	15 Oct 2020 15:27:47

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'tachycardia'	Mikayla Frye (b) (4)	27 Oct 2020 16:48:36
DataPoint activated with code reason code Data required.	(b) (4) Mikayla Frye (b) (4)	27 Oct 2020 16:47:34
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4) (b) (4)	15 Oct 2020 15:27:47

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '6.25'	Mikayla Frye (b) (4)	27 Oct 2020 16:48:36
DataPoint activated with code reason code Data required.	Mikayla Frye (b) (4)	27 Oct 2020 16:47:34
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	15 Oct 2020 15:27:47

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'mg (mg)'	Mikayla Frye (b) (4)	27 Oct 2020 16:48:36
DataPoint activated with code reason code Data required.	(b) (4) Mikayla Frye (b) (4)	27 Oct 2020 16:47:34
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4) (b) (4)	15 Oct 2020 15:27:47

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:39

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Mikayla Frye (b) (4)	27 Oct 2020 16:48:36
DataPoint activated with code reason code Data required.	(b) (4) Mikayla Frye (b) (4)	27 Oct 2020 16:47:34
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4) (b) (4)	15 Oct 2020 15:27:47

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'twice daily (BID)'	Mikayla Frye (b) (4)	27 Oct 2020 16:48:36
DataPoint activated with code reason code Data required.	(b) (4) Mikayla Frye (b) (4)	27 Oct 2020 16:47:34
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4) (b) (4)	15 Oct 2020 15:27:47

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Mikayla Frye (b) (4)	27 Oct 2020 16:48:36
DataPoint activated with code reason code Data required.	(b) (4) Mikayla Frye (b) (4)	27 Oct 2020 16:47:34
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4) (b) (4)	15 Oct 2020 15:27:47

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4)	27 Oct 2020 16:48:36
DataPoint activated with code reason code Data required.	(b) (4) Mikayla Frye (b) (4)	27 Oct 2020 16:47:34
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4) (b) (4)	15 Oct 2020 15:27:47

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Mikayla Frye (b) (4)	27 Oct 2020 16:48:36
DataPoint activated with code reason code Data required.	(b) (4) Mikayla Frye (b) (4)	27 Oct 2020 16:47:34
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4) (b) (4)	15 Oct 2020 15:27:47

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '26 Oct 2020'	Mikayla Frye (b) (4)	27 Oct 2020 16:48:36
DataPoint activated with code reason code Data required.	(b) (4) Mikayla Frye (b) (4)	27 Oct 2020 16:47:34
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4) (b) (4)	15 Oct 2020 15:27:47

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '0'	Mikayla Frye (b) (4)	27 Oct 2020 16:48:36
DataPoint activated with code reason code Data required.	(b) (4) Mikayla Frye (b) (4)	27 Oct 2020 16:47:34
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4) (b) (4)	15 Oct 2020 15:27:47

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Yes (Y)'	Mikayla Frye (b) (4)	27 Oct 2020 16:48:36
DataPoint activated with code reason code Data required.	(b) (4) Mikayla Frye (b) (4)	27 Oct 2020 16:47:34
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4) (b) (4)	15 Oct 2020 15:27:47

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Mikayla Frye (b) (4)	27 Oct 2020 16:48:36
DataPoint activated with code reason code Data required.	(b) (4) Mikayla Frye (b) (4)	27 Oct 2020 16:47:34
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4) (b) (4)	15 Oct 2020 15:27:47

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Mikayla Frye (b) (4)	27 Oct 2020 16:48:36
DataPoint activated with code reason code Data required.	(b) (4) Mikayla Frye (b) (4)	27 Oct 2020 16:47:34
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4) (b) (4)	15 Oct 2020 15:27:47

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	27 Oct 2020 16:48:36
DataPoint activated with code reason code Data required.	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:47:34
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4) (b) (4)	15 Oct 2020 15:27:47

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:48:36
DataPoint activated with code reason code Data required.	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:47:34
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4) (b) (4)	15 Oct 2020 15:27:47

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 16:48:36
DataPoint activated with code reason code Data required.	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:47:34
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4) (b) (4)	15 Oct 2020 15:27:47

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:39

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'Please add Atenolol, per source. Thank you !' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 17:25:43
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: ANTITHYROID PREPARATIONS, ATC: SULFUR-CONTAINING IMIDAZOLE DERIVATIVES, PRODUCT: THIAMAZOLE, PRODUCTSYNONYM: METHIMAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:42:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:42:41
Query 'Please add Atenolol, per source. Thank you !' answered with 'Atenolol is prescribed to start on 30Oct. Will add date once it has occurred. ' (Site from CRA).	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 18:27:22
Data point term sent to Coder	System	28 Oct 2020 17:34:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User opened query 'Please add Atenolol, per source. Thank you !' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 17:34:05
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: ANTITHYROID PREPARATIONS, ATC: SULFUR-CONTAINING IMIDAZOLE DERIVATIVES, PRODUCT: THIAMAZOLE, PRODUCTSYNONYM: METHIMAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 16:50:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 16:50:40
Data point term sent to Coder	System	27 Oct 2020 16:49:56
User entered 'methimazole'	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:49:06

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:49:06

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'hyperthyroidism'	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:49:06

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '30'	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:49:06

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'mg (mg)'	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:49:06

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:49:06

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'once daily (QD)'	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:49:06

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:49:06

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:49:06

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:49:06

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '26 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:49:06

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:49:06

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:49:06

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:49:06

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:49:06

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:49:06

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:49:06

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 16:49:06

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:39

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'Please add Methimazole 30mg daily PO start date 26Oct- ongoing, per source. ' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 03:10:48
Query 'Please add Methimazole 30mg daily PO start date 26Oct- ongoing, per source. ' answered with 'please see con med #13' (Site from CRA).	Heather Douds (b) (4)	13 Nov 2020 20:07:25
User opened query 'Please add Methimazole 30mg daily PO start date 26Oct- ongoing, per source. ' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 18:53:09
Query 'Please add Methimazole 30mg daily PO start date 26Oct- ongoing, per source. Also indication for Methimazole is hyperthyroidism . Since this condition is not listed in subject's medical history, please consider capturing this as an AE. Thank you! ' canceled (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 18:52:54
User opened query 'Please add Methimazole 30mg daily PO start date 26Oct- ongoing, per source. Also indication for Methimazole is hyperthyroidism . Since this condition is not listed in subject's medical history, please consider capturing this as an AE. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 18:51:33
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:18:28
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 19:47:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 19:47:56
Data point term sent to Coder	System	28 Oct 2020 18:26:55
User entered 'Atenolol'	Cassandra Zehenny (b) (4)	28 Oct 2020 18:26:53

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:18:30
User entered 'No (N)'	Cassandra Zehenny (b) (4)	28 Oct 2020 18:26:53

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:18:32
User entered 'Tachycardia'	Cassandra Zehenny (b) (4)	28 Oct 2020 18:26:53

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:18:33
User entered '25'	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 18:26:53

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:18:35
User entered 'mg (mg)'	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 18:26:53

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:18:36
User entered empty.	Cassandra Zehenny (b) (4)	28 Oct 2020 18:26:53
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:18:38
User entered 'twice daily (BID)'	Cassandra Zehenny (b) (4)	28 Oct 2020 18:26:53

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:18:39
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 18:26:53

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:18:41
User entered 'Oral (ORAL)'	Cassandra Zehenny (b) (4)	28 Oct 2020 18:26:53

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:18:43
User entered empty.	Cassandra Zehenny (b) (4)	28 Oct 2020 18:26:53
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:18:44
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	30 Oct 2020 17:02:28
User entered '30 Oct 2020' reason for change: Data Entry Error	Joan Siegner (b) (4)	30 Oct 2020 17:02:28
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	28 Oct 2020 18:26:53
User entered empty.	Cassandra Zehenny (b) (4)	28 Oct 2020 18:26:53

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:18:46
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 18:26:53

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:53:59
DataPoint Un-verified.	Stanley Doublin (b) (4)	19 Nov 2020 13:29:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	19 Nov 2020 13:29:42
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:18:49
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	28 Oct 2020 18:26:53

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:01
DataPoint Un-verified.	Stanley Doublin (b) (4)	19 Nov 2020 13:29:42
User entered '09 Nov 2020' reason for change: Data Entry Error	(b) (4)	19 Nov 2020 13:29:42
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:18:50
User entered empty.	Cassandra Zehenny (b) (4)	28 Oct 2020 18:26:53

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:18:52
User entered 'No (N)'	Cassandra Zehenny (b) (4)	28 Oct 2020 18:26:53

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	28 Oct 2020 18:26:53

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 18:26:53

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Oct 2020 18:26:53

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:05
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: ANTITHYROID PREPARATIONS, ATC: SULFUR-CONTAINING IMIDAZOLE DERIVATIVES, PRODUCT: THIAMAZOLE, PRODUCTSYNONYM: METHIMAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 13:32:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 13:32:01
Data point term sent to Coder	System	19 Nov 2020 13:31:13
User entered 'methimazole'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:30:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:11
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:30:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:12
User entered 'hyperthyroidism'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:30:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:14
User entered '30'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:30:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:15
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:30:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:17
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:30:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:20
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:30:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:22
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:30:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:23
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:30:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:24
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:30:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:26
User entered '26 Oct 2020'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:30:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:27
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:30:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:28
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:30:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:30
User entered '09 Nov 2020'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:30:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:31
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:30:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 13:30:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 13:30:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 13:30:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:36:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:38
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 13:32:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 13:32:57
Data point term sent to Coder	System	19 Nov 2020 13:32:14
User entered 'atenolol'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:36:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:40
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:36:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:41
User entered 'tachycardia'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:36:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:43
User entered '50'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:36:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:44
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:36:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:57
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:36:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:58
User entered 'twice daily (BID)'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:36:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:00
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:36:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:01
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:36:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:03
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:04
User entered '09 Nov 2020'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:06
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:36:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:36:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:08
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:36:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:10
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:36:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:36:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:17
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: ANTITHYROID PREPARATIONS, ATC: SULFUR-CONTAINING IMIDAZOLE DERIVATIVES, PRODUCT: THIAMAZOLE, PRODUCTSYNONYM: METHIMAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 13:41:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 13:41:01
Data point term sent to Coder	System	19 Nov 2020 13:40:22
User entered 'methimazole'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:36:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:18
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:36:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:20
User entered 'hyerthyroidism'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:36:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:21
User entered '40'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:36:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:23
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:36:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:24
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:36:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:31
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:36:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:32
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:36:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:33
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:36:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:35
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:36
User entered '09 Nov 2020'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:38
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:36:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:39
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:36:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:41
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:36:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:42
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:36:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:36:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:50
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 13:41:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 13:41:00
Data point term sent to Coder	System	19 Nov 2020 13:40:23
User entered 'benadryl'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:40:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:36:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:52
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:40:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:36:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:53
User entered 'itching'	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:40:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:36:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:55
User entered '25'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:40:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:36:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:56
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:40:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:36:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:58
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:40:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:36:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:00
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:40:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:36:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:02
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:40:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:36:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:03
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:40:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:36:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:04
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:40:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:06
User entered '09 Nov 2020'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:40:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:07
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:40:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:36:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:08
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:40:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:36:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:09
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:40:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:36:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:11
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:40:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:36:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 13:40:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 13:40:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 13:40:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:36:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:20
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) (b) (4)	19 Nov 2020 13:41:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 13:41:58
Data point term sent to Coder	System	19 Nov 2020 13:41:24
User entered 'influenza vaccine'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:40:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:36:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:21
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:40:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:36:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:22
User entered 'influenza prophylaxis'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:40:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:36:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:24
User entered '1'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:40:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:36:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:25
User entered 'Other (OTHER)'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:40:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:36:39

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:27
User entered 'injection'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:40:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:36:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:28
User entered 'once (ONCE)'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:40:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:36:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:29
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:40:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:36:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:31
User entered 'Intramuscular (INTRAMUSCULAR)'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:40:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:36:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:32
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:40:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:36:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:34
User entered '30 Oct 2020'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:40:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:36:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:35
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:40:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:36:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:37
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:40:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:36:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:38
User entered '30 Oct 2020'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:40:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:36:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:39
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:40:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:36:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 13:40:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 13:40:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:36:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 13:40:55

US3552191

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:36:39

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:26:09
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 15:31:36

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'USA-US089-2020-MRNA-1273-P301000009'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:28
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'sharon'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'frey'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:44
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 18:34:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:34:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:04
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:34
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:06
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:36
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'MO'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:47
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:08
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:39
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

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Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:35
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:30:21
User entered 'US'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE-USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	24 Nov 2020 02:55:43
User entered '12'	System	20 Nov 2020 21:48:13
User entered '11'	System	12 Nov 2020 14:28:04
User entered '10'	System	10 Nov 2020 19:08:45
User entered '9'	System	29 Oct 2020 15:07:38
User entered '8'	System	26 Oct 2020 13:05:43
User entered '7'	System	22 Oct 2020 17:23:57
User entered '6'	System	16 Oct 2020 00:20:24
User entered '5'	System	15 Oct 2020 12:44:51
User entered '4'	System	15 Oct 2020 12:28:57
User entered '3'	System	13 Oct 2020 15:24:38
User entered '2'	System	13 Oct 2020 13:30:31
User entered '1'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'USA-US089-2020-MRNA-1273-P301000009'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

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Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:28
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

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Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

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Folder: SAE USA-US089-2020-MRNA-1273-P301000009

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[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'sharon'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'frey'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:44
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 18:34:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:34:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:04
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:34
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:06
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:36
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'MO'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:47
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:08
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:39
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:35
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:30:21
User entered 'US'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE-USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	24 Nov 2020 02:55:43
User entered '12'	System	20 Nov 2020 21:48:13
User entered '11'	System	12 Nov 2020 14:28:04
User entered '10'	System	10 Nov 2020 19:08:45
User entered '9'	System	29 Oct 2020 15:07:38
User entered '8'	System	26 Oct 2020 13:05:43
User entered '7'	System	22 Oct 2020 17:23:57
User entered '6'	System	16 Oct 2020 00:20:24
User entered '5'	System	15 Oct 2020 12:44:51
User entered '4'	System	15 Oct 2020 12:28:57
User entered '3'	System	13 Oct 2020 15:24:38
User entered '2'	System	13 Oct 2020 13:30:31
User entered '1'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:36:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:12:56
User entered '12/Oct/2020 08:43'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:36:39

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)	05 Nov 2020 21:12:57
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:30:21
User entered '1'	(b) (4), (b) (6)	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

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[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'USA-US089-2020-MRNA-1273-P301000009'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:28
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'sharon'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'frey'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:44
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 18:34:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:34:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:04
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:34
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:06
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:36
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'MO'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:47
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:08
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:39
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:35
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:30:21
User entered 'US'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	24 Nov 2020 02:55:43
User entered '12'	System	20 Nov 2020 21:48:13
User entered '11'	System	12 Nov 2020 14:28:04
User entered '10'	System	10 Nov 2020 19:08:45
User entered '9'	System	29 Oct 2020 15:07:38
User entered '8'	System	26 Oct 2020 13:05:43
User entered '7'	System	22 Oct 2020 17:23:57
User entered '6'	System	16 Oct 2020 00:20:24
User entered '5'	System	15 Oct 2020 12:44:51
User entered '4'	System	15 Oct 2020 12:28:57
User entered '3'	System	13 Oct 2020 15:24:38
User entered '2'	System	13 Oct 2020 13:30:31
User entered '1'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:36:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:13:19
User entered '13/Oct/2020 13:30'	System	13 Oct 2020 13:30:31

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:36:39

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)	05 Nov 2020 21:13:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 15:24:05
User entered '1'	(b) (4), (b) (6)	13 Oct 2020 13:30:31

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'USA-US089-2020-MRNA-1273-P301000009'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:28
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'sharon'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'frey'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:44
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 18:34:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:34:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:04
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:34
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:06
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:36
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'MO'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:47
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:08
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:39
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:35
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:30:21
User entered 'US'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	24 Nov 2020 02:55:43
User entered '12'	System	20 Nov 2020 21:48:13
User entered '11'	System	12 Nov 2020 14:28:04
User entered '10'	System	10 Nov 2020 19:08:45
User entered '9'	System	29 Oct 2020 15:07:38
User entered '8'	System	26 Oct 2020 13:05:43
User entered '7'	System	22 Oct 2020 17:23:57
User entered '6'	System	16 Oct 2020 00:20:24
User entered '5'	System	15 Oct 2020 12:44:51
User entered '4'	System	15 Oct 2020 12:28:57
User entered '3'	System	13 Oct 2020 15:24:38
User entered '2'	System	13 Oct 2020 13:30:31
User entered '1'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:36:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:13:13
User entered '13/Oct/2020 15:24'	System	13 Oct 2020 15:24:38

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:36:39

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)	05 Nov 2020 21:13:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 15:29:45
User entered '1'	(b) (4), (b) (6)	13 Oct 2020 15:24:38

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'USA-US089-2020-MRNA-1273-P301000009'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:28
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'sharon'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'frey'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:44
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 18:34:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:34:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:04
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:34
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:06
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:36
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'MO'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:47
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:08
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:39
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:35
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:30:21
User entered 'US'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE-USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	24 Nov 2020 02:55:43
User entered '12'	System	20 Nov 2020 21:48:13
User entered '11'	System	12 Nov 2020 14:28:04
User entered '10'	System	10 Nov 2020 19:08:45
User entered '9'	System	29 Oct 2020 15:07:38
User entered '8'	System	26 Oct 2020 13:05:43
User entered '7'	System	22 Oct 2020 17:23:57
User entered '6'	System	16 Oct 2020 00:20:24
User entered '5'	System	15 Oct 2020 12:44:51
User entered '4'	System	15 Oct 2020 12:28:57
User entered '3'	System	13 Oct 2020 15:24:38
User entered '2'	System	13 Oct 2020 13:30:31
User entered '1'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:36:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:13:40
User entered '15/Oct/2020 08:28'	System	15 Oct 2020 12:28:57

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:36:39

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)	05 Nov 2020 21:13:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:29:01
User entered '1'	(b) (4), (b) (6)	15 Oct 2020 12:28:57

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'USA-US089-2020-MRNA-1273-P301000009'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:28
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'sharon'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'frey'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:44
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 18:34:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:34:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:04
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:34
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:06
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:36
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'MO'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:47
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:08
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:39
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:35
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:30:21
User entered 'US'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE-USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	24 Nov 2020 02:55:43
User entered '12'	System	20 Nov 2020 21:48:13
User entered '11'	System	12 Nov 2020 14:28:04
User entered '10'	System	10 Nov 2020 19:08:45
User entered '9'	System	29 Oct 2020 15:07:38
User entered '8'	System	26 Oct 2020 13:05:43
User entered '7'	System	22 Oct 2020 17:23:57
User entered '6'	System	16 Oct 2020 00:20:24
User entered '5'	System	15 Oct 2020 12:44:51
User entered '4'	System	15 Oct 2020 12:28:57
User entered '3'	System	13 Oct 2020 15:24:38
User entered '2'	System	13 Oct 2020 13:30:31
User entered '1'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:36:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:13:48
User entered '15/Oct/2020 08:44'	System	15 Oct 2020 12:44:51

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:36:39

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)	05 Nov 2020 21:13:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:20:15
User entered '1'	(b) (4), (b) (6)	15 Oct 2020 12:44:51

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'USA-US089-2020-MRNA-1273-P301000009'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:28
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'sharon'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'frey'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:44
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 18:34:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:34:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:04
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:34
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:06
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:36
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'MO'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:47
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:08
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:39
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:35
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:30:21
User entered 'US'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE-USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	24 Nov 2020 02:55:43
User entered '12'	System	20 Nov 2020 21:48:13
User entered '11'	System	12 Nov 2020 14:28:04
User entered '10'	System	10 Nov 2020 19:08:45
User entered '9'	System	29 Oct 2020 15:07:38
User entered '8'	System	26 Oct 2020 13:05:43
User entered '7'	System	22 Oct 2020 17:23:57
User entered '6'	System	16 Oct 2020 00:20:24
User entered '5'	System	15 Oct 2020 12:44:51
User entered '4'	System	15 Oct 2020 12:28:57
User entered '3'	System	13 Oct 2020 15:24:38
User entered '2'	System	13 Oct 2020 13:30:31
User entered '1'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 09:36:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:13:58
User entered '15/Oct/2020 20:20'	System	16 Oct 2020 00:20:24

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 09:36:39

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)	05 Nov 2020 21:13:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:23:32
User entered '1'	(b) (4), (b) (6)	16 Oct 2020 00:20:24

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'USA-US089-2020-MRNA-1273-P301000009'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:28
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'sharon'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'frey'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:44
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 18:34:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:34:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:04
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:34
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:06
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:36
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'MO'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:47
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:08
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:39
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:35
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:30:21
User entered 'US'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	24 Nov 2020 02:55:43
User entered '12'	System	20 Nov 2020 21:48:13
User entered '11'	System	12 Nov 2020 14:28:04
User entered '10'	System	10 Nov 2020 19:08:45
User entered '9'	System	29 Oct 2020 15:07:38
User entered '8'	System	26 Oct 2020 13:05:43
User entered '7'	System	22 Oct 2020 17:23:57
User entered '6'	System	16 Oct 2020 00:20:24
User entered '5'	System	15 Oct 2020 12:44:51
User entered '4'	System	15 Oct 2020 12:28:57
User entered '3'	System	13 Oct 2020 15:24:38
User entered '2'	System	13 Oct 2020 13:30:31
User entered '1'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (7)

Generated On: 26 Nov 2020 09:36:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:14:05
User entered '22/Oct/2020 17:23'	System	22 Oct 2020 17:23:57

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (7)

Generated On: 26 Nov 2020 09:36:39

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)	05 Nov 2020 21:14:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:24:10
User entered '1'	(b) (4), (b) (6)	22 Oct 2020 17:23:57

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'USA-US089-2020-MRNA-1273-P301000009'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:28
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'sharon'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'frey'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:44
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 18:34:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:34:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:04
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:34
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:06
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:36
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'MO'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:47
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:08
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:39
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:35
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:30:21
User entered 'US'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE-USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	24 Nov 2020 02:55:43
User entered '12'	System	20 Nov 2020 21:48:13
User entered '11'	System	12 Nov 2020 14:28:04
User entered '10'	System	10 Nov 2020 19:08:45
User entered '9'	System	29 Oct 2020 15:07:38
User entered '8'	System	26 Oct 2020 13:05:43
User entered '7'	System	22 Oct 2020 17:23:57
User entered '6'	System	16 Oct 2020 00:20:24
User entered '5'	System	15 Oct 2020 12:44:51
User entered '4'	System	15 Oct 2020 12:28:57
User entered '3'	System	13 Oct 2020 15:24:38
User entered '2'	System	13 Oct 2020 13:30:31
User entered '1'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (8)

Generated On: 26 Nov 2020 09:36:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:14:18
User entered '26/Oct/2020 13:05'	System	26 Oct 2020 13:05:43

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (8)

Generated On: 26 Nov 2020 09:36:39

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)	05 Nov 2020 21:14:20
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:07:28
User entered '1'	(b) (4), (b) (6)	26 Oct 2020 13:05:43

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'USA-US089-2020-MRNA-1273-P301000009'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:28
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'sharon'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'frey'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:44
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 18:34:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:34:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:04
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:34
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:06
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:36
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'MO'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:47
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:08
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:39
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:35
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:30:21
User entered 'US'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE-USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	24 Nov 2020 02:55:43
User entered '12'	System	20 Nov 2020 21:48:13
User entered '11'	System	12 Nov 2020 14:28:04
User entered '10'	System	10 Nov 2020 19:08:45
User entered '9'	System	29 Oct 2020 15:07:38
User entered '8'	System	26 Oct 2020 13:05:43
User entered '7'	System	22 Oct 2020 17:23:57
User entered '6'	System	16 Oct 2020 00:20:24
User entered '5'	System	15 Oct 2020 12:44:51
User entered '4'	System	15 Oct 2020 12:28:57
User entered '3'	System	13 Oct 2020 15:24:38
User entered '2'	System	13 Oct 2020 13:30:31
User entered '1'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (9)

Generated On: 26 Nov 2020 09:36:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:14:34
User entered '29/Oct/2020 11:07'	System	29 Oct 2020 15:07:38

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (9)

Generated On: 26 Nov 2020 09:36:39

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)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:14:39
User entered '1'	(b) (4), (b) (6)	29 Oct 2020 15:07:38

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'USA-US089-2020-MRNA-1273-P301000009'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:28
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'sharon'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'frey'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:44
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 18:34:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:34:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:04
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:34
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:06
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:36
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'MO'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:47
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:08
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:39
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:35
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:30:21
User entered 'US'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE-USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	24 Nov 2020 02:55:43
User entered '12'	System	20 Nov 2020 21:48:13
User entered '11'	System	12 Nov 2020 14:28:04
User entered '10'	System	10 Nov 2020 19:08:45
User entered '9'	System	29 Oct 2020 15:07:38
User entered '8'	System	26 Oct 2020 13:05:43
User entered '7'	System	22 Oct 2020 17:23:57
User entered '6'	System	16 Oct 2020 00:20:24
User entered '5'	System	15 Oct 2020 12:44:51
User entered '4'	System	15 Oct 2020 12:28:57
User entered '3'	System	13 Oct 2020 15:24:38
User entered '2'	System	13 Oct 2020 13:30:31
User entered '1'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (10)

Generated On: 26 Nov 2020 09:36:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:37
User entered '10/Nov/2020 19:08'	System	10 Nov 2020 19:08:45

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (10)

Generated On: 26 Nov 2020 09:36:39

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)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:35
User entered '1'	(b) (4), (b) (6)	10 Nov 2020 19:08:45

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'USA-US089-2020-MRNA-1273-P301000009'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:28
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'sharon'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'frey'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:44
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 18:34:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:34:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:04
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:34
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:06
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:36
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'MO'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:47
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:08
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:39
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:35
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:30:21
User entered 'US'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE-USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	24 Nov 2020 02:55:43
User entered '12'	System	20 Nov 2020 21:48:13
User entered '11'	System	12 Nov 2020 14:28:04
User entered '10'	System	10 Nov 2020 19:08:45
User entered '9'	System	29 Oct 2020 15:07:38
User entered '8'	System	26 Oct 2020 13:05:43
User entered '7'	System	22 Oct 2020 17:23:57
User entered '6'	System	16 Oct 2020 00:20:24
User entered '5'	System	15 Oct 2020 12:44:51
User entered '4'	System	15 Oct 2020 12:28:57
User entered '3'	System	13 Oct 2020 15:24:38
User entered '2'	System	13 Oct 2020 13:30:31
User entered '1'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (11)

Generated On: 26 Nov 2020 09:36:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:49
User entered '12/Nov/2020 14:28'	System	12 Nov 2020 14:28:04

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (11)

Generated On: 26 Nov 2020 09:36:39

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)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:50
User entered '1'	(b) (4), (b) (6)	12 Nov 2020 14:28:04

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'USA-US089-2020-MRNA-1273-P301000009'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:28
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'sharon'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'frey'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:44
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 18:34:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:34:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:04
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:34
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:06
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:36
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'MO'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:47
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:08
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:39
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:35
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:30:21
User entered 'US'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE-USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	24 Nov 2020 02:55:43
User entered '12'	System	20 Nov 2020 21:48:13
User entered '11'	System	12 Nov 2020 14:28:04
User entered '10'	System	10 Nov 2020 19:08:45
User entered '9'	System	29 Oct 2020 15:07:38
User entered '8'	System	26 Oct 2020 13:05:43
User entered '7'	System	22 Oct 2020 17:23:57
User entered '6'	System	16 Oct 2020 00:20:24
User entered '5'	System	15 Oct 2020 12:44:51
User entered '4'	System	15 Oct 2020 12:28:57
User entered '3'	System	13 Oct 2020 15:24:38
User entered '2'	System	13 Oct 2020 13:30:31
User entered '1'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (12)

Generated On: 26 Nov 2020 09:36:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:00:31
User entered '20/Nov/2020 21:48'	System	20 Nov 2020 21:48:13

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (12)

Generated On: 26 Nov 2020 09:36:39

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)	24 Nov 2020 15:00:32
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 02:55:32
User entered '1'	(b) (4), (b) (6)	20 Nov 2020 21:48:13

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'USA-US089-2020-MRNA-1273-P301000009'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:28
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'sharon'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'frey'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:44
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 18:34:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:34:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:04
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:34
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:06
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:36
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'MO'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:47
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:08
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:39
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:48:35
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:30:21
User entered 'US'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE-USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	24 Nov 2020 02:55:43
User entered '12'	System	20 Nov 2020 21:48:13
User entered '11'	System	12 Nov 2020 14:28:04
User entered '10'	System	10 Nov 2020 19:08:45
User entered '9'	System	29 Oct 2020 15:07:38
User entered '8'	System	26 Oct 2020 13:05:43
User entered '7'	System	22 Oct 2020 17:23:57
User entered '6'	System	16 Oct 2020 00:20:24
User entered '5'	System	15 Oct 2020 12:44:51
User entered '4'	System	15 Oct 2020 12:28:57
User entered '3'	System	13 Oct 2020 15:24:38
User entered '2'	System	13 Oct 2020 13:30:31
User entered '1'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (13)

Generated On: 26 Nov 2020 09:36:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:00:36
User entered '23/Nov/2020 21:55'	System	24 Nov 2020 02:55:43

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (13)

Generated On: 26 Nov 2020 09:36:39

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)	24 Nov 2020 15:00:37
User entered '1'	(b) (4), (b) (6)	24 Nov 2020 02:55:43